IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), *Plaintiffs*, v. JONATHAN SKRMETTI, in his official capacity as ATTORNEY GENERAL OF THE STATE OF TENNESSEE, *Defendant*.	Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Pharmacyclics LLC, Allergan Sales, LLC (collectively "AbbVie" or "Plaintiffs"), by and through their undersigned attorneys, bring this action for declaratory and injunctive relief against the Attorney General of the State of Tennessee, challenging the applicability and constitutionality of S.B. 1414, to be codified at TN Code § 47-18-136. In support, AbbVie alleges as follows:

PRELIMINARY STATEMENT

1. AbbVie brings this lawsuit to challenge the constitutionality of S.B. 1414—a recently enacted Tennessee law that requires AbbVie to transfer its pharmaceutical products to certain commercial pharmacies at substantially discounted prices on pain of criminal penalties. In so doing, Tennessee's statute violates the Supremacy Clause by impermissibly changing the terms of a federal drug-pricing regime—the federal 340B program—and significantly increasing the cost

of participation in that regime. In addition, S.B. 1414 effects an unconstitutional taking in violation of the Takings Clause of the Fifth Amendment, unlawfully discriminates against or unduly burdens interstate commerce in violation of the Commerce Clause, as established by Dormant Commerce Clause principles, is unconstitutionally vague in violation of the Due Process Clause, and violates the First Amendment's Free Speech and Petition Clauses.

2. S.B. 1414 arises out of a long-running dispute about the requirements that the federal 340B program places upon drug manufacturers. In short, the federal 340B statute, 42 U.S.C. § 256b, establishes a comprehensive program that requires pharmaceutical manufacturers to offer their drugs at statutorily set and significantly reduced prices to a list of fifteen specifically enumerated types of healthcare providers known as "covered entities." Opting into the 340B program and making these offers of drugs at the significantly reduced prices is required for manufacturers who want to participate in federal Medicaid and Medicare programs. *See* 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5).

3. Under the 340B statute, manufacturers are required only to "offer" their drugs to covered entities at the 340B price—not "sell" them ***unconditionally***. 42 U.S.C. § 256b(a)(1). That is, the 340B statute requires only that manufacturers make an offer at a particular price to a particular set of covered entities but preserves the liberty of manufacturers to insist upon other non-price terms. And commercial pharmacies, like Walgreens and CVS, are not among the 340B statute's list of entities entitled to an "offer" of the 340B price.

4. The federal statute grants the Secretary of the U.S. Department of Health and Human Services ("HHS") ***exclusive*** authority to enforce its provisions. *See* 42 U.S.C. § 256b(d). The statute leaves no role for states or other third parties to change the requirements of the federal 340B program or the conditions it imposes on manufacturers in return for participating in

Medicaid. Nor do states or other third parties have any authority to enforce the federal statute's requirements. The Supreme Court has held that third-party enforcement "would undermine the agency's efforts to administer" the 340B program and other related federal programs "harmoniously and uniformly." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 119–20 (2011).

5. Further, because forcing manufacturers to transfer their drugs at discounted prices to covered entities would raise serious constitutional concerns, Congress did not mandate participation in the 340B program outright and instead tied it to a voluntary choice: participation in Medicaid and Medicare. And to further incentivize manufacturer participation in 340B—*i.e.*, to prevent the cost of participation from becoming too high—Congress carefully limited the program and adopted certain safeguards to ensure that manufacturers' discounted drugs would be used to help needy patients, rather than become a buy-low, sell-high scheme for commercial entities. For example, in a statutory provision designed to prevent "diversion," Congress prohibited covered entities from transferring manufacturers' reduced-price drugs to anyone other than the entity's own patients. *See* 42 U.S.C. § 256b(a)(5)(B). In effect, that provision prohibits other commercial entities from either participating in the 340B program or profiting from the sale of manufacturers' drugs at the 340B discounted price.

6. Nevertheless, over the last decade covered entities have entered into novel contractual arrangements with commercial pharmacies (called "contract pharmacies") that have allowed those pharmacies to profit from the sale of manufacturers' drugs. Instead of serving the covered entities' uninsured and low-income patients, the for-profit contract pharmacies acquire manufacturers' drugs at the federally discounted price, sell them to patients (including indigent patients) at full price, and pocket the difference. Contract pharmacies accomplish this arbitrage

through a complicated accounting system known as the "replenishment model," described in more detail below. The bottom-line result is that for-profit commercial pharmacies and the covered entities they contract with are able to pocket billions of dollars every year, splitting the profits at the expense of both manufacturers and the needy patients who are supposed to be served by the federal 340B program.

7. Neither contract pharmacies nor the replenishment model are features of the ordinary commercial drug-distribution system in the United States, outside the 340B context, where they are unauthorized by statute. AbbVie is involved in no other commercial arrangement using contract pharmacies or the replenishment model. Contract pharmacies and the replenishment model are creatures only of the federal 340B drug discount arbitrage regime.

8. In response to these abuses—and because Congress left room for manufacturers to impose reasonable conditions on their 340B offers—manufacturers (including AbbVie) have exercised that right by implementing policies that effectively condition the sale or transfer of drugs at 340B-discounted prices to covered entities and their affiliated contract pharmacies. AbbVie's policy reflects the reality that the federal statute requires only that manufacturers "offer" their drugs at discounted prices to the covered entities. It does not compel unconditional sales, nor does it require manufacturers to transfer 340B-discounted drugs wherever and to whomever a covered entity demands. And it certainly does not require manufacturers to subsidize commercial pharmacy ***profits*** under the guise of 340B compliance.

9. Manufacturers' decisions to address these abuses resulted in litigation between manufacturers and HHS and, in early 2023, the U.S. Court of Appeals for the Third Circuit confirmed that the manufacturers' policies are lawful and permitted under federal law. Again, Congress required manufacturers to ***offer*** their covered outpatient drugs at discounted prices in

return for participating in Medicaid; it did not impose any additional obligation on manufacturers to provide their drugs to third-party commercial pharmacies, or to otherwise support arbitrage of their charitable discounts. Commercial pharmacies are not covered entities, and they are not entitled to benefit from the federal 340B program or access manufacturers' drugs at the 340B-discounted price. *See Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023).

10. In May 2024, the United States Court of Appeals for the District of Columbia Circuit agreed with the Third Circuit's conclusion, holding that because "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount," the statute gives manufacturers freedom "to impose at least some delivery conditions." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). And because conditions such as limiting delivery to "a single contract pharmacy designated by the covered entity" in no way impair a manufacturer's offer to sell drugs at the 340B-discounted price, the restrictions fall within the ambit of freedom manufacturers enjoy under the federal 340B statute. *Id.* at 462–64.

11. Numerous states participated in the Third Circuit and D.C. Circuit cases as an *amici curiae*, on the losing side. After that loss, many states turned to their own legislatures to propose and implement legislation to reach their desired 340B outcomes and attempt to impose requirements under the federal 340B statute that Congress chose not to impose. S.B. 1414 is an example of one such piece of legislation.

12. In particular, S.B. 1414 not only eliminates manufacturers' federally preserved ability to impose reasonable conditions on their 340B offers—it imposes new conditions on Medicare and Medicaid participation that Congress never authorized. *See Novartis*, 102 F.4th at

460 ("[W]e think that this silence ***preserves***—rather than abrogates—the ability of sellers to impose at least some delivery conditions." (emphasis added)). For one, S.B. 1414 prohibits manufacturers from "directly or indirectly deny[ing], impos[ing] any restrictions or prohibitions on, discriminat[ing] against, or otherwise limit[ing] the ***acquisition*** . . . or delivery of a 340B drug" to any contract pharmacy "authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity[.]" S.B. 1414, § 1(c) (emphasis added). The text of the law effectively transfers to covered entities ***and commercial pharmacies*** unfettered authority to demand manufacturers' property at significantly reduced prices for the benefit of private parties of their choice.

13. To be clear, the harm AbbVie challenges in this action arises not from the federal 340B program or the replenishment model itself, but from S.B. 1414's prohibition on manufacturers' ability to condition their federal 340B offers. Even in the absence of the replenishment model, Tennessee's law would injure manufacturers like AbbVie because S.B. 1414 would still compel AbbVie to transfer its drugs at confiscatory prices under conditions AbbVie would not agree to and beyond what the federal statute requires as a matter of Medicare and Medicaid participation. AbbVie's injury stems from the state's law expansion of AbbVie's obligations—not from the design or administration of the 340B program.

14. This state-imposed harm—compelling manufacturers to transfer their drugs at discounted prices on terms not required by federal law and to which AbbVie would not agree—cannot stand because it violates the United States Constitution. S.B. 1414 should be enjoined.

15. ***First***, S.B. 1414 is preempted by federal law under the Supremacy Clause. The doctrine of federal preemption requires that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (quoting *Felder v. Casey*, 487 U.S. 131,

138 (1988)). S.B. 1414 seeks to regulate pricing where it purports to prohibit manufacturers from "directly or indirectly deny[ing], impos[ing] any restrictions or prohibitions on, discriminat[ing] against, or otherwise limit[ing] the acquisition . . . or delivery of a 340B drug" to any contract pharmacy "authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity[.]" S.B. 1414, § 1(c). By seeking to change the requirements of when and to which entities manufacturers must offer drugs at a discounted price as a condition of participating in the federal Medicaid program, S.B. 1414 unlawfully modifies the requirements of the federal 340B program. S.B. 1414 conflicts with the objectives of the 340B statute, imposing requirements on drug manufacturers that conflict with the actual requirements of the 340B statute, thereby raising the costs of Medicaid participation above those set by Congress and deterring manufacturers from that participation. S.B. 1414 also blocks manufacturers from accessing the administrative dispute resolution system created by federal law, manufacturers' only avenue for redress of abuses of the 340B program, by barring manufacturers from demanding claims data or conducting audits of covered entities. And finally, S.B. 1414 impermissibly injects the Attorney General, armed with state law penalties and other remedies, and even private citizens into what Congress intended to be an exclusively federal scheme.

16. ***Second***, even if S.B. 1414 is not preempted as a matter of federal law, it deprives manufacturers of property without due process of law and results in an impermissible taking under the Fifth Amendment. Under the Fifth Amendment, made applicable to the states through the Fourteenth Amendment, neither the federal government nor the states have any authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of A for the sole purpose of transferring it to another private party B, even though A is paid just

compensation"). Because the U.S. Constitution prohibits the government from forcing the transfer of property at confiscatory prices to private parties for their own private benefit, *see* U.S. Const. amend. V, the federal government has defended the federal 340B statute on grounds that manufacturers are not being ***forced*** to transfer their property to for-profit pharmacies, but instead supposedly agreed to do so at the request of covered entities "voluntarily" in exchange for the benefit of participation in the federal Medicaid program. Tennessee has no such defense.

17. Tennessee purports to directly require manufacturers to transfer their property at steeply discounted prices to other private entities if those entities have ***third-party*** contracts that purport to allow them to access AbbVie's drugs at those deep discounts. S.B. 1414's text makes clear that it seeks to regulate "acquisition" of drugs at the 340B price. *See* S.B. 1414, §§ 1(a)(1), (c). Tennessee has no authority to take private property for private use, and no authority to deprive AbbVie of its property without due process of law. By seeking to change the requirements for when drug manufacturers must provide 340B-priced drugs to contract pharmacies at the request of covered entities, the statute unlawfully appropriates private property for the private benefit of commercial pharmacies and does so without serving any valid public purpose. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 370 (2015) (holding government's confiscation of portion of farmers' raisin crop for charitable or other purpose without just compensation was a *per se* taking).

18. ***Third***, S.B. 1414 is unconstitutionally vague. "It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (collecting cases). In determining whether a statute is unconstitutionally vague, a court evaluates whether (1) "regulated parties [] know what is required of them so they may act accordingly," and (2) the statute is "precis[e]" and provides the "guidance

[] necessary so that those enforcing the law do not act in an arbitrary or discriminatory way." *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012).

19. Tennessee's law fails on both fronts. For example, S.B. 1414 penalizes manufacturers for "[i]mpos[ing] any requirements relating to inventory management systems" and for imposing requirements that the Attorney General, in his full discretion, deems to "interfere" with a covered entity's access to 340B discounts. S.B. 1414, §§ 1(a)(3), (a)(6). Without clear notice of what constitutes an impermissible "requirement" or what conduct the attorney general will decide "interfere[s]" with a covered entity's access, manufacturers are left to guess at the statute's boundaries—under threat of civil liability and penalties. That is precisely what the Due Process Clause forbids.

20. ***Fourth***, S.B. 1414 violates the Commerce Clause, as interpreted by Supreme Court precedent applying the Dormant Commerce Clause doctrine. A state law cannot "directly regulate out-of-state transactions by those with no connection to the state." *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 376 n.1 (2023). But S.B. 1414 purports to do exactly that, because nowhere in the bill's text is there any requirement that the transactions it covers have ***any*** nexus to Tennessee. *See* S.B. 1414, § 1(g)(2) (defining "340B entity" as "a covered entity participating in the federal 340B drug discount program, as defined in section 340B of the Public Health Service Act, 42 U.S.C. § 256b, including the entity's pharmacy or pharmacies," without limiting the definition to Tennessee entities or pharmacies). Tennessee is attempting to compel manufacturers to act in accordance with Tennessee law outside of Tennessee. Separately, "nondiscriminatory burdens on commerce . . . that . . . clearly outweigh the benefits of a state or local practice" also violate the dormant Commerce Clause. *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 353 (2008) (citing *Pike v. Bruce Church Inc.*, 397 U.S. 137, 142 (1970)). The burden S.B. 1414 places on the

national prescription drug industry and the viability of the 340B program is excessive in relation to any legitimate benefits Tennessee could reap from it, because there are none—the effect of the bill is to actually harm 340B patients.

21. ***Fifth***, S.B. 1414 violates the First Amendment's Free Speech Clause and Petition Clause. The First Amendment protects AbbVie's right to speak about the 340B program, communicate with other entities about terms of 340B offers, and express its views about disputes over the execution of 340B contracts. It also protects AbbVie's right to seek redress for 340B grievances in the federal regulatory process. But S.B. 1414 unlawfully burdens those protected activities. The law outright prohibits AbbVie from asking a 340B entity to "clarify" its demand for reimbursement, S.B. 1414 §§ 1(a)(2), (g)(3), even though AbbVie cannot access the federal adjudicatory process without seeking such clarification. And S.B. 1414 also bars AbbVie from imposing "requirements" and "limitations" on 340B entities using broad, sweeping terms—terms that chill AbbVie's constitutionally protected right to communicate with prospective business partners, pharmacies, and the public. *Id.* § 1(a)(1). Tennessee advances no compelling or substantial interest with respect to those speech restrictions.

22. AbbVie seeks a declaration that S.B. 1414 is unconstitutional because it is preempted by federal law, constitutes an unconstitutional taking, is unconstitutionally vague, regulates exclusively out of state conduct in violation of the Commerce Clause, and unconstitutionally burdens its First Amendment rights. AbbVie further seeks injunctive relief barring the Tennessee Attorney General from enforcing S.B. 1414 against AbbVie.

PARTIES TO THE ACTION

23. AbbVie, Inc., a Delaware Corporation, is a global research-based biopharmaceutical company dedicated to addressing some of the world's most complex and

serious diseases, and advancing medical science in areas such as immunology, oncology, and neuroscience. Since 2012, AbbVie, Inc. has participated in the federal 340B drug discount program, helping uninsured and vulnerable patients obtain access to the medications they need. AbbVie's headquarters are located in North Chicago, Illinois. AbbVie, Inc. is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with the U.S. Department of Health and Human Services ("HHS") Health Resources and Services Administration ("HRSA").[1]

24. Allergan, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

25. Durata Therapeutics, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

26. AbbVie Products LLC, a Georgia Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

27. Pharmacyclics LLC, a Delaware Limited Liability Company, is a new party to this lawsuit, and a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

[1] On February 11, 2025, President Trump issued Executive Order 14210, titled "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative. *See* 90 Fed. Reg. 9,669. On March 27, 2025, HHS announced it intended to restructure, including by creating an Administration for a Healthy America ("AHA") which will have authority over, among other sub-agencies, HRSA. *See* Dep't of Health & Human Servs., *HHS Announces Transformation to Make America Healthy Again* (March 27, 2025), https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

28. Previously, Warner Chilcott Corporation merged with Allergan Sales, LLC and Allergan Sales, LLC is the surviving entity. Allergan Sales, LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

29. Defendant Jonathan Skrmetti is the Attorney General of the State of Tennessee. The Attorney General has general enforcement authority over Tennessee's Consumer Protection Act, and accordingly "may bring any appropriate action or proceeding in any court of competent jurisdiction pursuant to this part." TN Code § 47-18-114. This suit is brought against the Attorney General solely in his official capacity.

JURISDICTION AND VENUE

30. AbbVie's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution.

31. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 1332, and 28 U.S.C. § 1343(a)(3).

32. The Court has authority to grant injunctive and declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Court's inherent equitable powers, including the power to enjoin the actions of state officials if contrary to the United States Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159–60 (1908).

33. Venue is proper in this District under 28 U.S.C. § 1391(b) because this action challenges a Tennessee law that is applicable to AbbVie's sale and distribution of drugs at discounted prices under the federal 340B statute within this District. AbbVie sells and distributes drugs to multiple 340B covered entities within this District, and these entities purport to maintain contract pharmacy arrangements. Venue is also proper because Defendant maintains offices, through which he would enforce the challenged law, in the city of Nashville within this District.

GENERAL ALLEGATIONS

A. The 340B Drug Pricing Program

34. This case concerns section 340B of the federal Public Health Service Act, which created the federal "340B program" as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

35. The purpose of the federal 340B program is to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by creating "a low-cost source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

36. Before Congress created the 340B program, individual manufacturers voluntarily provided their drugs at reduced prices to institutions that served needy and vulnerable patients. In 1990, Congress passed a statute called the Medicaid Rebate Act, which had the unintended consequence of creating disincentives for manufacturers to continue providing those voluntary discounts. H.R. Rep. No. 102-384, pt. 2, at 9–10 (1992). Through the Veterans Health Care Act, Congress remedied that unintended disincentive and established the federal 340B program, turning the manufacturers' previous voluntary support into a federal mandate.

37. The 340B statute requires that any manufacturer that participates in the federal Medicaid Drug Rebate Program must "offer" its covered outpatient drugs "for purchase" at deeply discounted prices to eligible "covered entities"—disproportionate share hospitals and other service providers that are expected to serve predominantly low-income and vulnerable patients. 42 U.S.C. § 256b(a)(1).

38. The statute expressly limits participation in the 340B program to "covered entities." *See id.* § 256b(a)(4). The statute defines "covered entities" to include only organizations and service providers that predominantly serve low-income patients. The definition includes, for example, federally qualified health centers, children's hospitals, qualifying rural hospitals, and clinics that serve vulnerable patients. *Id*. For-profit commercial pharmacies are not included in the statutory list of "covered entities." *Id*. Nor does the 340B statute include any provision authorizing covered entities to purchase manufacturers' drugs and dispense them through commercial pharmacies. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."), *aff'd sub nom. Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).

39. The discounted 340B price for each of the manufacturer's drugs is calculated by subtracting the drug's Medicaid unit rebate amount from its Average Manufacturer Price, as determined under the federal Medicaid Drug Rebate Program, codified at section 1927 of the Social Security Act. 42 U.S.C. §§ 256b(a)(1)–(2) & (b). The resulting prices, called the 340B "ceiling prices," are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). Many mandatory 340B ceiling prices are as little as one penny per unit of drug.

40. To indicate their agreement to participate in the federal 340B program and comply with its requirements, manufacturers sign a form contract with HHS, called the Pharmaceutical Pricing Agreement ("PPA"). That agreement is drafted by HHS. It has "no negotiable terms,"

and it "incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 117–18.

41. The PPA imposes no obligation on participating manufacturers to make ***unconditional*** sales to covered entities. Additionally, the PPA neither requires manufacturers to sell discounted drugs to contract pharmacies nor to facilitate the transfer of their discounted drugs to contract pharmacies. Nor does it grant covered entities any right to obtain unfettered access to manufacturers' drugs at discounted prices through contract pharmacies.

42. Both the PPA and the federal 340B statute are structured to prevent commercial parties from participating in the federal 340B program or profiting from the sale of manufacturers' drugs at discounted prices. Over the past decade, however, that is exactly what has happened as a result of covered entities entering into contractual relationships with commercial pharmacies. Under these arrangements, instead of using manufacturers' deeply discounted drugs to treat the indigent and uninsured patients that visit a covered entity and receive healthcare services from the covered entity itself, commercial contract pharmacies sell manufacturers drugs at regular prices to pharmacy customers and then demand that their stocks be replenished with drugs purchased by the covered entity through the federal 340B program at discounted prices, pocketing the difference (the "spread") for their own financial benefit.

43. In recent years, commercial contract pharmacies have earned annually over $3.3 ***billion*** in "spread." *See* Eric Percher et al., Nephron Rsch. LLC, *The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption*, at 3, 30–31 (2020) (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone).

44. These abuses of the federal 340B program violate the letter and spirit of the federal 340B statute. Congress designed the 340B statute with the intent that there would be a close nexus

between the federal drug pricing program and its only valid public purpose—helping low-income and uninsured patients obtain access to medications at discounted prices. Consistent with that intent, the statute prevents covered entities from using manufacturers' drugs to generate commercial profits or letting the drugs be transferred or sold to benefit entities outside the program.

45. The statute expressly forbids "diversion" by prohibiting covered entities from selling or otherwise transferring any manufacturer's discounted drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

46. The statute also prohibits covered entities from receiving or causing "duplicate discounts or rebates." They may not obtain a 340B discount and cause a Medicaid rebate to be paid by the manufacturer for the same unit of drug. *Id*. § 256b(a)(5)(A).

47. S.B. 1414 unconstitutionally compels AbbVie to make sales under conditions it would not agree to, thereby enabling and perpetuating the very abuses federal law forbids.

48. The 340B statute imposes an affirmative duty on the Secretary of HHS—through authority delegated to HRSA—to protect the program's integrity by "provid[ing] for improvements in compliance by covered entities . . . in order to prevent diversion" and violations of the statute's duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

49. The statute provides mechanisms for resolving administrative disputes between manufacturers and covered entities through audits and a federal Administrative Dispute Resolution ("ADR") process. *See id.* §§ 256b(d)(l)(B)(v), (d)(3). Notably, HRSA recently issued a final rule setting forth additional details of the congressionally prescribed 340B ADR process. *See* 89 Fed. Reg. 28,643 (April 19, 2024). The final rule established a comprehensive scheme to resolve

disputes between manufacturers and covered entities arising under the 340B statute. Under the rule, a "340B ADR Panel" within HRSA is tasked with resolving not only disputes about drug prices but also "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price"—the exact issue S.B. 1414 seeks to address. *See* 42 C.F.R. §§ 10.3, 10.21; *accord id.* § 10.22(c)(1) ("A manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that facilitate the sale or distribution of its drugs to covered entities."); 89 Fed. Reg. 28,649 (April 19, 2024) ("HHS agrees and has further modified § 10.21(a)(1) to further explain that an overcharge claim generally includes claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price."); *id.* at 28,644 ("[T]he 340B Program is related to drug pricing and drug distribution.").

50. The statute entrusts enforcement of the 340B statute ***exclusively*** to the Secretary of HHS and details what penalties may apply. *See* 42 U.S.C. §§ 256b(a)(5)(C)–(D), (d)(l)(B)(v), (d)(3). As the Supreme Court reasoned in *Astra*, Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B program, and private enforcement by covered entities "would undermine the [HHS's] efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 119–20.

51. Failure to comply with the statutory requirements under the 340B program may result in termination of the PPA (and the manufacturer's ability to participate in Medicaid), federal enforcement actions, and potentially the imposition of large civil penalties. *See* 42 U.S.C. §§ 256b(a)(5)(D), (d)(1)(B)(vi), (d)(2)(B)(v), (d)(3)(A).

B. The Growth in Contract Pharmacy Arrangements

52. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities ***that lacked an in-house pharmacy*** from entering into a contractual

relationship with a ***single*** outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). The guidance made clear that it "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

53. Guidance documents, such as the 1996 guidelines, are by definition general statements of policy that are non-binding, non-enforceable, and do not create any legal rights or obligations. They are intended instead to inform the public as to how HRSA intends to exercise its enforcement discretion.

54. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated, for the first time, that the agency would allow covered entities to enter into contractual relationships with an ***unlimited*** number of "contract pharmacies," even if the covered entity had an in-house pharmacy of its own. 74 Fed. Reg. 10,272 (Mar. 5, 2010).

55. Like the 1996 guidance, the 2010 guidance did not impose binding obligations on manufacturers. Indeed, HRSA again made clear that the non-binding guidance created no new rights and imposed no new obligations. *See id.* at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law"). In other words, while HRSA indicated that it would not interpret the 340B statute to prohibit covered entities from using multiple contract pharmacies, it did not purport to impose any obligation on manufacturers to transfer drugs to contract pharmacies or otherwise facilitate covered entities' use of contract pharmacies.

56. Following issuance of the 2010 guidance, covered entities dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 12,000% between 2010 and 2024. *See* Elanor Blalock, *For-Profit Pharmacy Participation in the 340B Program:*

2024 Update, BRG 7 (Jan. 2025) ("BRG Report"), https://tinyurl.com/2k8daabf. As of 2023, over 33,000 pharmacy locations—"more than half of the entire U.S. pharmacy industry"—acted as 340B contract pharmacies, up from fewer than 1,300 pharmacy locations in 2010. *See* U.S. Senate Comm. on Health, Educ., Labor & Pensions, 118th Cong., *Congress Must Act To Bring Needed Reforms To The 340B Drug Pricing Program* 3 (Apr. 2025) ("Cassidy Report"), https://tinyurl.com/44c6w2en. This explosion in the use of contract pharmacies has been driven by the prospect of sharing in the outsized profit margins on manufacturer-subsidized 340B-discounted drugs. For example, in 2009 sales of 340B-priced drugs totaled just $4.2 billion, but by 2023 had increased by more than 30-fold to $124 billion. *See* Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC Schaeffer Cntr. For Health Pol'y & Econ. 5 (Oct. 2021) ("Mulligan"), https://tinyurl.com/y2fuv87u; Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, IQVIA 2 (2024), https://tinyurl.com/ywkdbbju.

57. Similarly, the number of covered entities participating in the program jumped from around 15,000 in 2010 to more than 50,000 by 2020. *See* Mulligan, *supra*, at 4; U.S. Gov't Accountability Off., *Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, at 23 (2019), https://www.gao.gov/assets/d20108.pdf ("Given the weaknesses in HRSA's oversight, some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible.").

58. Nor does the program's explosive growth correlate with an increase in indigent patients, or improvements in care. Indeed, since 2010, the percentage of uninsured patients in the United States has fallen by nearly 38%. *See* Kenneth Finegold et al., U.S. Dep't of Health & Hum.

Servs., Off. of the Assistant Sec'y for Planning & Evaluation, Trends in the U.S. Uninsured Population, 2010–2020, Issue Brief No. HP-2021-02, at 2 (Feb. 11, 2021), https://tinyurl.com/4rf9cm8t.

59. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe fiduciary duties to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts. Contract pharmacies are not "agents" of the covered entities; they are merely business partners. Indeed, large contract pharmacies like CVS and Walgreens charge "complex fees for pharmacy and administrative services to covered entities" that increase year over year. Cassidy Report, *supra*, at 18. Importantly, these arrangements do not exist outside the context of the federal 340B program, as there is no other context in which commercial pharmacies are able to share in the "spread" generated by selling manufacturers' discounted drugs to their customers at full prices.

60. Contract pharmacy arrangements generally use one of two inventory models: (1) pre-purchased inventory or (2) replenishment.

61. A few contract pharmacies use the pre-purchased inventory model, in which a covered entity's 340B-purchased drugs are kept in stock at the contract pharmacy, and when filling prescriptions on behalf of that covered entity, the contract pharmacy uses the covered entity's 340B-purchased inventory.

62. Most contract pharmacies, however, use what is known as the "replenishment" model. The replenishment model is, as covered entities self-describe it, "an accounting mechanism" by which they retroactively match discounts for the pharmacy with previously (full price) dispensing events to customers. *See AbbVie et al. v. Murrill*, No. 6:23-CV-01307-RRS-

CBW (W.D. La. June 6, 2024) ("*Murrill*"), Summ. J. Hr'g Tr. at 59-60 (Ron Connelly, counsel for the Louisiana Primary Care Association); 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). In practice, the replenishment model permits the "transfer" of 340B-priced drugs to contract pharmacies with the full knowledge that those drugs will be sold to any customer who comes in the door, whether 340B-eligible or not.

63. Under the replenishment model, no 340B-purchased drugs are kept in stock at the contract pharmacy. Instead, "the pharmacy has an initial stock of drugs" obtained through ordinary commercial purchases at the non-340B price (Figure 1, step 1). *See Murrill*, Summ. J. Hr'g Tr. at 60 (Ron Connelly, counsel for the Louisiana Primary Care Association). Initially, the contract pharmacy fills all prescriptions using its own non-340B purchased inventory (that is, full price inventory)—including those prescriptions issued by covered entities. As explained below, the pharmacy determines which previous dispenses were 340B eligible and once sufficient eligible dispenses for a particular drug accumulate, the covered entity orders additional quantities of that drug at the federal 340B price (Figure 1, step 6). The covered entity directs AbbVie to transfer those drugs to the contract pharmacy to "replenish" the non-340B-priced drugs dispensed by the contract pharmacy on the covered entity's behalf (Figure 1, step 2). *See* Decl. of RADM Krista M. Pedley, Dir., Off. of Pharmacy Affs., HRSA, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD, ECF No. 125-2 ¶¶ 3–11 (S.D. Ind.). Sometimes the contract pharmacy actually places the order on behalf of the covered entity for more drugs at the federal 340B price.

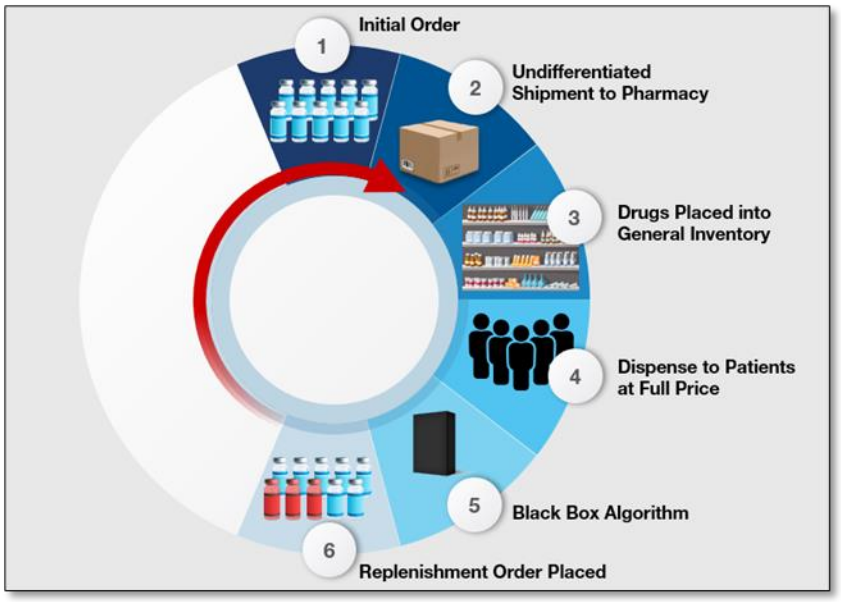

Figure 1. Replenishment Model Step-By-Step.

64. Once the contract pharmacy receives the replenishment order, the 340B-priced drugs are "placed on the shelf, become[] 'neutral inventory,' and may be dispensed to any subsequent patient" (Figure 1, step 3). *See id.* at ¶ 11.

65. 340B-discounted drugs are shipped, packaged, and delivered in the same manner as commercially priced drugs.

66. In other words, under the replenishment model, contract pharmacies do not keep a separate inventory of 340B-priced drugs but instead dispense drugs to both 340B and non-340B patients alike out of their general inventories. Nor do most contract pharmacies attempt to determine prior to or at the point of sale whether the patient is eligible for a 340B discounted drug. In almost all instances, contract pharmacies dispense the 340B-priced drugs to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient (Figure 1, step 4). The pharmacy or a third-party administrator ("TPA") carries out a 340B determination at the back end, well after a drug has been dispensed (and likely consumed) by the patient. This determination is made using a black box algorithm (unknown by AbbVie) based on

the contract pharmacy's own criteria, without any involvement from the covered entities (Figure 1, step 5). If those criteria are designed correctly, the post-sale determination may be able to calculate how many 340B-priced drugs AbbVie must sell. But in reality, the contract pharmacies' criteria often include prior patients, who no longer receive the 340B-discounted drugs at the pharmacy but that are included under a "once-a-patient-always-a-patient" approach, so the covered entity and its pharmacies are able to maximize the arbitrage profits from the 340B program. As the D.C. Circuit observed, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457–58.

67. Aside from diversion created by the pharmacies and covered entities' use of their own distorted criteria to mark otherwise 340B-ineligible sales as deserving the federally mandated low prices, the replenishment model encourages diversion by allowing covered entities to transfer federally discounted drugs to pharmacies, who are not "a patient of the entity." *See* 42 U.S.C. § 256b(a)(5)(B).

68. Although HRSA interpreted the federal 340B statute to allow the use of pharmacies, it did so because "[w]e believe that the relationship between the covered entity and the contract pharmacy is one of agency." 61 Fed. Reg. 43,549, 43,554 (Aug. 23, 1996). Additionally, HRSA noted that the covered entity purchases the drugs, and must retain title and responsibility for them even after directing shipment to the contract pharmacy. *Id.* at 43,553. However, in practice, covered entities do not retain title to the drugs.

69. As explained above, contract pharmacies (typically through a TPA) instruct covered entities to place orders—sometimes even placing the order itself, without going through

a covered entity—of additional quantities of drugs at the discounted 340B price to "replenish" the general inventories that they will use to supply non-340B-eligible sales. Significantly, as a result of such replenishment, even though the drugs are purchased by or on behalf of covered entities, contract pharmacies effectively take title to the drugs. At no point in time does a covered entity take title to the drugs under this model. *See Sanofi Sues HHS, HRSA for Contract Details Between Covered Entities, Contract Pharmacies*, 340B Report (June 18, 2024), https://tinyurl.com/bdmx88wu (according to a covered entity spokesperson, "in order for the replenishment model to function, 'the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory.'"). AbbVie is also not aware of any instance where a contract pharmacy or covered entity represents that an agency relationship exists between them such that the contract pharmacy acts at the direction of a principal covered entity.

70. In practice, therefore, covered entities and contract pharmacies share in the "spread" generated by selling the drugs at higher prices to pharmacy customers and/or seeking full commercial reimbursement from the patients' insurance plans. For-profit, commercial pharmacies thereby obtain significant profits from selling the 340B covered outpatient drugs that manufacturers must offer to covered entities at deeply discounted prices.

71. By dramatically expanding the pool of individuals who can access the discounted drugs that covered entities can buy at discounted prices—including individuals who do not qualify as patients of the covered entity—covered entities and commercial pharmacies can obtain profits that extend far beyond Congress's intent when it created the 340B program. One study found that in 2018 alone, covered entities and their contract pharmacies generated approximately $64 billion in estimated gross profits from the purchase of manufacturers' drugs at mandated 340B prices. *See* BRG Report, *supra*, at 7. And a recent report from the U.S. Senate Committee on Health,

Education, Labor & Pensions found that a covered entity in Virginia generated $276.5 million in 340B savings and revenue from September 2018 through September 2023, while another covered entity in Ohio accrued $933.7 million in 340B savings and revenue from April 2020 through June 2023. Cassidy Report, *supra*, at 6.

72. When commercial pharmacies are brought into the program, there is a significantly greater risk that manufacturers' discounted drugs will be dispensed to individuals who are not "patients" of the covered entity. As HHS has found, contract pharmacy arrangements "create complications in preventing diversion" (for example, contract pharmacies cannot verify patient eligibility in real-time like a covered entity can). HHS Office of Inspector General, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 1 (2014) ("HHS Report"), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

73. Because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. *See* U.S. Gov't Accountability Off., *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 44 (June 2018), https://www.gao.gov/assets/d18480.pdf (noting that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies); *id.* at 35, 43–44 (finding 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies; and many of the remaining 55% reported rarely giving discounts to patients obtaining medicines through contract pharmacies).

74. Covered entities and commercial pharmacies reap windfalls from gaining access to manufacturers' drugs at deeply discounted prices under the federal 340B program, but uninsured and underinsured patients are not benefitting. *See* HHS Report, at 2 (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Cassidy Report, *supra*, at 9 (explaining that the covered entities under investigation "do not pass 340B discounts directly to their patients and differ on how patients receive discounts on their 340B drugs"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020), https://tinyurl.com/yxehpc7v (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the product away"); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, IQVIA 12 (Sept. 27, 2022), https://tinyurl.com/2wdtuh52 ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum 2 (June 17, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

75. For example, the North Carolina Department of the State Treasurer published a recent report explaining that "some hospitals are using the 340B program to enrich themselves

rather than to serve vulnerable communities," and "instead . . . expanded into wealthier neighborhoods with a higher percentage of insured individuals who pay more for the drugs." Dale R. Folwell, N.C. Dep't of State Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program*, N.C. State Health Plan 3, https://tinyurl.com/4cy8an69. 46% of Tennessee's contract pharmacies are located in affluent neighborhoods. *See* Pioneer Institute Public Policy Research, *340B in Tennessee* ("340B in Tennessee"), https://tinyurl.com/329ycz3n.

76. While commercial pharmacies are driving massive growth in the 340B program—at double-digit annual rates—charity care by hospitals has decreased. Commentators have noted, for example, that as the 340B program has grown at a remarkable rate, the total value of hospitals' uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program, 7–8 (Oct. 30, 2020), https://tinyurl.com/4s5ptxxy; Adam J. Fein, *EXCLUSIVE: 340B Program Purchases Reach $24.2 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019), https://drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-30Oct2020.pdf.

77. Both the New York Times and Wall Street Journal have run exposés describing the flaws in contract pharmacy arrangements, flaws that enable large scale arbitrage and damage the very communities that the federal 340B program was designed to help. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, NY Times (Sept. 24, 2022), https://tinyurl.com/3sbxuswa (describing how one 340B hospital "has been slashing services at Richmond Community while investing in the city's wealthier, white neighborhoods, according to more than 20 former executives, doctors and nurses"); Anne Wilde Mathews et al., *Many Hospitals Get Big Drug*

Discounts. That Doesn't Mean Markdowns for Patients, Wall. St. J. (Dec. 22, 2022), https://tinyurl.com/yc2uc6yp ("The data show that hospitals often extend their 340B discounts to clinics in well-off communities, where they can charge privately insured patients more than those on Medicaid" which "raise questions about the program's growth and purpose").

78. A recent New York Times investigation into Apexus, the government contractor managing 340B drug pricing, exposed systemic price manipulation, lack of oversight, and financial exploitation within contract pharmacy arrangements—allowing for significant financial abuse at the expense of the communities the program was meant to protect. Apexus, which is responsible for negotiating better prices and access to mediations, has a direct financial incentive to expand the program and maximize hospital profits. Because Apexus "is allowed to collect a fee for almost every drug sold under the program," it has actively developed strategies to drive 340B sales and increase covered entity revenue. These strategies include training covered entities on how to maximize 340B revenue; operating a "purchasing optimization team" advising hospitals on which drugs to generate the highest margins; and running a certification program teaching hospitals how to capture more patients and prescriptions under 340B. These tactics have prioritized profit generation over patient benefit, increasing Apexus's and covered entities' financial gains at the expense of patients, insurers, and manufacturers. Hospitals face no restrictions on which outpatient prescriptions they classify as 340B, allowing them to mine patient records from as far back as 36 months to claim additional patients under the program—even if those patients never directly benefit from the discounts. In some cases, hospitals have passed inflated drug costs onto patients instead of sharing the savings. *See* Ellen Gabler, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 15, 2025), https://tinyurl.com/33ftpfdf.

79. Congress has also expressed concern over growing abuses in the 340B program. On April 24, 2025, the Majority Staff of the Senate Health, Education, Labor & Relations Committee ("Senate HELP Committee"), Chaired by Senator Cassidy, released a report titled "Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program,"—the culmination of a nearly two-year investigation into contract pharmacy arrangements and other 340B-related issues. In its findings, the Senate HELP Committee determined that not only have contract pharmacies grown by sheer numbers, *see supra* ¶ 56, but major commercial pharmacy chains like CVS, Walgreens, Express Scripts, OptumRx, and Walmart, account for 75% of all contract pharmacy relationships. *See* Cassidy Report, *supra*, at 3.

80. As part of the Senate HELP Committee's investigation, several covered entities expressly told Congress that they do not pass on discounts to patients, and do not specifically account for 340B revenue in their budgets. *See id.* at 10. And large commercial pharmacy chains like CVS and Walgreens disclosed that they collect significant fees associated with 340B dispensing. For example, for patients with third-party insurance, CVS collects between $35-$85 per brand-name drug dispensing event depending on the days-supply of the prescription dispensed. *Id.* CVS reported to the Committee that in 2023 it made $382 million in 340B-related dispensing fees and "annual gross and net revenues generated from the 340B program." *Id.*, App. 106.

81. While the replenishment model contributes to the abuses described above—issues manufacturers are rightfully trying to address—S.B. 1414 goes further: it mandates that manufacturers sell or transfer discounted drugs on terms Congress never required and that manufacturers never agreed to. The injuries manufacturers face under S.B. 1414 do not stem from the 340B program itself or even from the replenishment model specifically, but from the state's attempt to override federal law and impose ***state*** requirements on AbbVie's participation in a

federal program. Even if the replenishment model were eliminated entirely, S.B. 1414 would still compel manufacturers to transfer property under conditions they oppose, stripping them of their federally acknowledged ability to impose reasonable limitations on their 340B offers. In doing so, S.B. 1414 not only conflicts with federal law—it also effects a taking. The statute forces manufacturers to sell valuable property at below-market rates, to third parties, with no room to impose conditions or decline a sale. That is AbbVie's injury. The abuses simply underscore the stakes.

C. Manufacturers' Response to HRSA's Overreach

82. AbbVie and other manufacturers have exercised their lawful right to decline covered entity requests that manufacturers provide their discounted 340B-priced drugs to an unlimited number of commercial pharmacies.

83. AbbVie has implemented initiatives making clear that it will not indiscriminately accept requests that it transfer 340B-discounted drugs to an unlimited number of third-party commercial contract pharmacies servicing covered entities.

84. As 340B abuse continued to grow, with covered entities seeking the provision of 340B-priced drugs to an excessive number of for-profit pharmacies—sometimes located more than 100 miles from the covered entity's location—AbbVie updated its policy to place reasonable limits around provision to contract pharmacies. Specifically, if a covered entity has its own in-house pharmacy, AbbVie's policy now is to only take orders for the in-house pharmacy. However, if a covered entity does not have an in-house pharmacy capable of dispensing to outpatients, AbbVie will take orders for one designated contract pharmacy, provided that the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site, and the covered entity submits limited claims data on 340B utilization for that pharmacy location. In addition, Grantee Covered Entities may use an unlimited number of contract pharmacies as long as the Grantee

registers with 340B ESP™, a web-based platform made available to covered entities at no cost and submit claims data.[2] *See* Ltr. from E. Scheidler to 340B Covered Entities (Feb. 27, 2025), https://tinyurl.com/mr2rac4u.

85. In implementing its initiatives, AbbVie has confirmed that it will continue to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute. *See* 42 U.S.C. § 256b(a)(1). AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's 340B-discounted drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

86. In addition to AbbVie, many other pharmaceutical manufacturers have adopted policies directed at addressing abuses of the 340B program by covered entities and contract pharmacies. Like AbbVie's, these policies do not refuse to supply drugs at discounted prices under the federal 340B program solely because the covered entity has an arrangement with a number of contract pharmacies; instead, they are directed at addressing program abuses.

87. AbbVie's policy is not only consistent with those upheld by the Third and D.C. Circuits but also gives covered entities and contract pharmacies more convenience at its own expense. *See Sanofi*, 58 F.4th at 701; *Novartis*, 102 F.4th at 463–64.

88. AbbVie's compelled compliance is directly attributable to Tennessee's enactment of S.B. 1414, which took effect upon the Governor's signature on May 5, 2025. *Id.* at § 4.

[2] "Claims data," as used in the administration of the 340B program, refers to prescription-level information necessary to determine whether a drug is subject to a 340B discount, a Medicaid rebate, or both, and whether the recipient is a patient of a covered entity.

D. Litigation in Federal Courts

89. HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See* Tom Mirga, *HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), https://340breport.com/hrsa-says-its-340b-contract-pharmacy/. HHS then reversed its position and attempted to impose a new obligation on manufacturers.

90. On December 30, 2020, HHS issued a final decision—labeled an "Advisory Opinion"—that for the first time ever purported to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* U.S. Dep't of Health & Hum. Servs., Advisory Op. No. 20-06, Contract Pharmacies Under the 340B Program, at 1 (Dec. 30, 2020), https://tinyurl.com/2ca6rmnm. Various manufacturers brought suit in early 2021 to challenge this HHS decision.

91. On May 17, 2021, the government sent certain manufacturers "violation" letters purporting to enforce the 340B statute. AbbVie received a violation letter on October 17, 2022, stating that HHS had made a final determination that AbbVie's policy violated the 340B statute by not agreeing to transfer 340B discounted drugs to unlimited contract pharmacies because "AbbVie's actions have resulted in overcharges." *See* U.S. Dep't of Health & Hum. Servs., Violation Letter to AbbVie (Oct. 17, 2022), https://tinyurl.com/47ybp3kw.

92. While the December 30 decision was later withdrawn following a ruling from the federal district court for the district of Delaware, *see AstraZeneca*, 543 F. Supp. 3d at 47, the previously issued violation letters were not withdrawn.

93. Several of Tennessee's sister states filed amicus briefs in the Third and D.C. Circuit Courts of Appeals in support of HHS, expressing disapproval of the manufacturers' policies. *See* Corrected Brief of Amicus Curiae States, *Novartis*, 102 F.4th 452 (No. 21-5299, filed May 23,

2022); Brief of Amicus Curiae, *Sanofi Aventis*, 58 F.4th 696 (3d Cir. 2023) (No. 21-3167, ECF No. 34).

94. On January 30, 2023, the Third Circuit issued a decision recognizing that Congress intentionally "chose not to" impose delivery-related obligations on manufacturers, explaining that the federal 340B statute's plain text suggests that Congress intended "one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *See Sanofi*, 58 F.4th at 704.

95. The Third Circuit further found that manufacturers' policies do not prevent covered entities from participating in the 340B program or entering into contractual relationships with commercial pharmacies. Under manufacturers' policies, covered entities "can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy." *Id*. at 703.

96. The Third Circuit rejected the argument that manufacturers were not permitted to address program abuses, such as diversion and duplicate discounting, by imposing restrictions on when they will transfer drugs to commercial pharmacies.

97. On May 21, 2024, the District of Columbia Circuit issued its own opinion endorsing the same view, holding that "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*,102 F.4th at 460. As a result, as long as a manufacturer's policy "neither precludes [it] from making a bona fide 'offer' nor increases its contract 'price'"—such as only "deliver[ing] section 340B drugs to a covered entity's in-house pharmacy or to a single contract pharmacy designated by the covered entity"—the condition is legitimate and may be enforced without running afoul of section 340B. *Id.* at 463–64.

98. In the face of those federal decisions, several states enacted their own laws trying to achieve what HHS could not. Those state laws—passed in Arkansas, Louisiana, Maryland, Mississippi, Missouri, West Virginia, South Dakota, North Dakota, Utah, and others—try to limit manufacturers' ability to condition the federal offer by forcing them to transfer their drugs to an unlimited number of contract pharmacies at the 340B-discounted prices. A new round of federal litigation commenced. Manufacturers challenged the laws as unconstitutional on several grounds, and that litigation continues today.

99. Some courts have allowed the state laws to take effect. *See, e.g.*, *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024) (Arkansas). By contrast, a Southern District of West Virginia court preliminarily enjoined West Virginia's contract pharmacy law, holding the law unconstitutionally conflicted with section 340B. *PhRMA v. Morrisey*, 2024 WL 5147643, at *7-12 (S.D. W. Va Dec. 17, 2024). The West Virginia court found that laws like Tennessee's S.B. 1414 regulate "price, not delivery." *Id.* at *8. Under such laws, "[t]he question is only about what price the pharmacy and the covered entity will pay." *Id.* In other words, "the system is about delivery *at a given price*, not delivery *per se*." *Id.*

100. Other cases await decisions in district court, and multiple appeals are now pending before the United States Courts of Appeals for the Fourth and Fifth Circuits.

E. The Tennessee Law

101. While the federal courts were deciding that the federal 340B statute grants manufacturers the freedom to adopt policies to combat abuse of the 340B program by contract pharmacies, Tennessee turned to its own legislature to enact a law that purports to take that freedom away.

102. In February 2025, the Tennessee legislature introduced legislation to limit manufacturers' right to attach reasonable conditions to the federal 340B offer made to covered

entities. As of April 22, 2025, S.B. 1414 had passed both legislative chambers and Governor Bill Lee signed it into law on May 5, 2025.

103. The text of S.B. 1414 makes clear that changing the terms of the federal 340B program and compelling a private wealth transfer of 340B-priced drugs from one party to another, are its regulatory objects. After providing that a "340B drug" is "a covered outpatient drug within the meaning of 42 U.S.C. § 256b; is eligible for any offer for reduced prices by a manufacturer under 42 U.S.C. § 256b(a)(1); and is purchased by a 340B entity or would have been purchased by a 340B entity," S.B. 1414 goes on to define "340B entity" by referencing 42 U.S.C. § 256b, the federal 340B statute. *See* S.B. 1414, §§ 1(g)(1), (2). In other words, the Tennessee statute cannot exist outside the context of the federal 340B program.

104. S.B. 1414 directly eliminates manufacturers' ability to adopt policies to prevent 340B abuse or prevent the taking of their own property by entities not otherwise entitled to it: "A drug manufacturer . . . shall not, either directly or indirectly deny, impose any restrictions or prohibitions on, discriminate against, or otherwise limit the acquisition . . . or delivery of a 340B drug" to any contract pharmacy "authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity[.]" S.B. 1414, § 1(c).

105. Although S.B. 1414 contains a grandfather-like provision, stating that "subsection (c) does not apply to any requirements, prohibitions, limitations, or restrictions in place on or before June 1, 2025," *id.* in practice, AbbVie's policy likely cannot qualify for the exception. Indeed, the provision affords manufactures like AbbVie little to no benefit. In passing S.B. 1414, Tennessee becomes the 13th state to enact its own different and distinct versions of these contract pharmacy protections. As the number of state laws increases, *see supra* [Chart paragraph], manufacturers must frequently amend and revise their policies to comply with the various

prohibitions and requirements in those states. Where Tennessee's law has no limit on its extraterritorial scope, that means anytime AbbVie changes its policy to reflect a new state law—even thousands of miles from Tennessee—in doing so AbbVie could fall outside the "protection" of § 1(c).

106. Upon information and belief, AbbVie intends to revise its current contract pharmacy policies in South Dakota and North Dakota, on July 1, 2025 and August 1, 2025—the two state law's respective effective dates. Because that means AbbVie's policy will change "on or after July 1, 2025," the "protections" afforded by § 1(c) are no protection at all.

107. Further, the state statute imposes a series of restrictions on manufacturers' right to request claims data including that a "drug manufacturer . . . shall not, either directly or indirectly . . . [i]mpose additional requirements or limitations on a 340B entity, including requiring the submission of any health information, claims or utilization data, purchasing data, payment data, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless such data submission is explicitly required by the United States department of health and human services or applicable state law." *Id.* § 1(a)(1).

108. Not only does the statute restrict access to this data, but it also prohibits drug manufactures from "directly or indirectly…[r]equir[ing] a 340B entity to reverse, ***resubmit, or clarify*** a claim after the initial adjudication unless these actions are in the normal course of business ***and not related to the 340B program***[.]" *Id.* § 1(a)(2).

109. The statute similarly prohibits manufacturers from imposing any requirements relating to "inventory management systems of 340B drugs," "the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities," and

"accreditation, recertification, credentialing, or recredentialing that are not imposed on pharmacies or providers that are not 340B entities." *Id.* §§ 1(a)(3), (4), (5).

110. And if there were any doubt about the breadth of S.B. 1414, the statute imposes a catch-all provision, prohibiting manufacturers from "[i]mpos[ing] ***any*** requirement determined by the [Attorney General of Tennessee] to interfere with the ability of a 340B entity to access discounts provided under the 340B program." *Id.* § 1(a)(6).

111. S.B. 1414 thus prevents manufacturers from collecting basic claims and utilization data from covered entities—data that covered entities are already generating and sharing with their third-party vendors. *See* Senate HELP Rep. at 19 (explaining CVS's contract pharmacy agreement "specifically requires [the covered entity] to use a CVS Health subsidiary, Wellpartner, as its 340B administrative services provider (TPA) for contract pharmacy services transactions at CVS pharmacies and to pay related administrative fees, adding another layer of revenue for the parent pharmacy company (CVS)."); *accord id.* at App. 87 (explaining Wellpartner assists covered entities with "ESP data submissions"). This data allows manufacturers to monitor illegal diversion and duplicate discounting, and, critically, it is the sole means by which manufacturers may access the audit and ADR process. For similar reasons, a federal West Virginia court has already preliminarily enjoined West Virginia's 340B statute containing a similar prohibition on claims data requests. *Morrisey*, 2024 WL 5147643, at *7-12.

112. Finally, S.B. 1414 grants access to AbbVie's drugs at the 340B ceiling price for ***any*** "location" contracting with a 340B entity, thus expanding the pool of entities authorized by Congress to receive drugs purchased at the 340B prices by granting access to all "340B entit[ies] ***or other location[s]*** that [are] under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity[.]" *See* S.B. 1414, § 1(c) (emphasis added); *see*

also id. § 1(g)(2) (expanding the definition of "340B entity" to include a covered entity as defined under the federal 340B statute, and "the entity's pharmacy or pharmacies").

113. The statute cites no source, under the 340B statute or elsewhere, that authorizes Tennessee to add requirements to the conditions for participating in the federal 340B program, to add contract pharmacies to the list of enumerated covered entities, to compel the transfer of AbbVie's property at confiscatory prices for private use, or to establish an enforcement process for the State's Attorney General to seek remedies for alleged violations of the federal 340B requirements.

114. Violations of S.B. 1414 are Class B misdemeanors and are considered "unfair or deceptive act[s] or practice[s] affecting trade or commerce." S.B. 1414, § 1(d)(1); *see also* TN Code § 47-18-104(a). As a result, "a civil penalty may be assessed in the amount of fifty thousand dollars ($50,000) per violation," and "[e]ach package of 340B drugs applicable to a violation of subsection (a) or (c) constitutes a separate violation." *Id.* §§ 1(d)(1), (2).

115. The Attorney General also has the power to "bring an action in the name of the state against" violators of S.B. 1414 § 1(a) and (c) "to restrain by temporary restraining order, temporary injunction, or permanent injunction the use of such act or practice." TN Code § 47-18-108(a)(1).

116. Lastly, S.B. 1414 takes advantage of the Tennessee Consumer Protection Act's private right of action for "[a]ny person who suffers an ascertainable loss of money or property…as a result of the use or employment by another person of an unfair or deceptive act or practice." TN Code § 47-18-109(a)(1); S.B. 1414 § 2. Thus, after S.B. 1414, private citizens in Tennessee will be permitted to bring actions for damages against drug manufacturers to enforce Tennessee's expansion of the federal 340B program.

117. Put together, S.B. 1414 authorizes the Tennessee Attorney General to use the full extent of his powers to impose severe consequences on pharmaceutical manufacturers who fail to comply with covered entities' demands that they transfer 340B-priced drugs to any "340B entity or other location that is under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity" including fines and injunctions. *See* S.B. 1414 §§ 1(c), (d); TN Code §§ 47-18-108(a)(1), 109(a)(1).

118. S.B. 1414 purports to limit its scope in subsections (a) and (c), stating that the law's provisions do not apply where federal law prohibits or requires otherwise. *See* § 1(a)(1) (stating that a drug manufacturer shall not "impose additional requirements or limitations on a 340B entity … ***unless such data submission is explicitly required by the United States department of health and human services or applicable state law***"); *id.* § 1(c) (stating that a drug manufacturer shall not "deny, impose any restrictions or prohibitions on, discriminate against, or otherwise limit the acquisition of a 340B drug . . . ***unless such receipt is prohibited by the United States department of health and human services or applicable state law***").

119. But there is no way to harmonize S.B. 1414 with the 340B statute. Federal law leaves no role for states to regulate the transfer of 340B-priced drugs to pharmacies who are not permitted as a matter of federal law to participate in the federal program and obtain access to manufacturers' drugs at discounted prices. These specific provisions of S.B. 1414 conflict with Section 340B's requirements for drug manufacturers, as well as its exclusive federal enforcement scheme, and fly in the face of foundational constitutional principles.

STANDING

120. AbbVie is injured by S.B. 1414 because S.B. 1414 imposes state-level requirements not mandated by Congress and that directly conflict with and frustrate the federal 340B program. S.B. 1414 overrides the discretion manufacturers retain under federal law to

impose reasonable conditions on their 340B offers, and subjects AbbVie to conflicting obligations, compliance burdens, and potential enforcement actions. The law also forces AbbVie to provide its private property to another private party in a prohibited A-to-B wealth transfer. Moreover, the law subjects AbbVie to the Attorney General's enforcement of the Act's requirements. Plaintiffs are signatories to 340B PPAs, and/or are successors-in-interest to executed 340B PPAs, with HRSA.

121. AbbVie's injuries are fairly traceable to S.B. 1414 because the state statute compels a private transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies—in the absence of any recognized public use or purpose. S.B. 1414 compels sales at the discounted price against AbbVie's wishes and on terms it would not agree to; in other words, in the absence of S.B. 1414, those sales or other transfers to covered entities and their contract pharmacies at the discounted price ***would not occur***. The statute prohibits' AbbVie from enforcing its contract pharmacy policy, which otherwise conditions the sale or transfer of 340B-discounted drugs. S.B. 1414 thus compels a transaction that would not take place but for the state's law. Put differently, the existence and enforcement of S.B. 1414 results in the difference between a sale at the discounted price occurring or not. In addition, the statute seeks to impose new state law obligations on drug manufacturers participating in the 340B program beyond those required by the federal statute. Neither section 340B, nor any existing regulation, nor the PPA, contains these requirements. Moreover, the Act purports to grant the Attorney General and private citizens authority to enforce the Act in a way that violates federal law and infringes on AbbVie's property rights.

122. A favorable ruling is likely to address AbbVie's injuries. Enjoining the provisions of S.B. 1414 that unconstitutionally force the taking of manufacturers' private property for no

public use would redress AbbVie's injuries because AbbVie's property would not be unconstitutionally taken, and AbbVie would not be exposed to state-imposed penalties for exercising its rights under the 340B program and the Constitution. Similarly, a declaratory judgment would redress AbbVie's injuries because AbbVie would not be exposed to enforcement actions and accumulating penalties.

BASIS FOR INJUNCTIVE RELIEF

123. Harm is irreparable when the injury "is not fully compensable by monetary damages." *Certified Rest. Dry Cleaning Network, LLC v. Tenke Corp.*, 511 F.3d 535, 550 (6th Cir. 2007) (citation omitted) (reversing district court's denial of preliminary injunction). Irreparable harm exists when a plaintiff challenging a law is "likely to incur unrecoverable compliance costs" absent an injunction—financial losses rendered "irreparable" by barriers to recovery like a government defendant's sovereign immunity. *Tennessee v. Dep't of Educ.*, 104 F.4th 577, 613 (6th Cir. 2024) (quoting *Kentucky v. Biden*, 57 F.4th 545, 556 (6th Cir. 2023)); *see also In re MCP No. 185*, 2024 WL 3650468 (6th Cir. Aug. 1, 2024) (citing "unrecoverable compliance costs" as irreparable harm); *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 765 (2021) ("The moratorium [on collecting rent during COVID-19 pandemic] has put the applicants, along with millions of landlords across the country, at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery.").

124. Forcing AbbVie to comply with or subject itself to state enforcement proceedings under Tennessee's unconstitutional law would necessarily impose irreparable harm on AbbVie. "The choice between threatened enforcement or complying with an unconstitutional law rises to the level of an irreparable injury." *McLemore v. Gumucio*, 2019 WL 3305131 (M.D. Tenn. July 23, 2019) (granting preliminary injunction).

125. AbbVie is also harmed by the abridgment of its speech and right to petition the government, in violation of the First Amendment. Indeed, the "caselaw of this circuit has long recognized that a violation of a person's constitutional rights is, in and of itself, an irreparable harm." *Bongo Productions, LLC v. Lawrence*, 548 F. Supp. 3d 666, 685 (M.D. Tenn. 2021); *see also, e.g., Obama for Am. v. Husted*, 697 F.3d 423, 436 (6th Cir. 2012) ("When constitutional rights are threatened or impaired, irreparable injury is presumed.").

126. Moreover, a taking occurs each and every time a drug manufacturer is required against its own volition to transfer its drugs at the 340B-discounted price to a commercial pharmacy for the private benefit of that for-profit pharmacy. Effecting an unconstitutional taking of AbbVie's private property in a forced transfer to another private party for no recognized public use or purpose constitutes an irreparable injury. *See, e.g.*, *Obama for Am.*, 697 F.3d at 436.

127. Further, if S.B. 1414 is not enjoined as applied to AbbVie, AbbVie would be exposed to additional state law requirements as a condition of participating in the federal 340B program and would risk violating S.B. 1414 simply by performing its federally mandated functions. A party may be irreparably injured in the face of the threatened enforcement of a preempted law. *See, e.g.*, *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

128. If drug manufacturers such as AbbVie are required to provide their drugs to contract pharmacies, the magnitude of the economic loss is beyond the capacity of Tennessee to compensate with damages. Discounted purchases under the program reached approximately $66.3 billion for fiscal year 2023 in the U.S. *See* Health Res. & Servs. Admin., *2023 340B Covered Entity Purchases* (Oct. 2024), https://tinyurl.com/56nzphvm.

129. The cost to AbbVie of complying with state laws like Tennessee's is substantial. AbbVie estimates that, for example, the cost of complying with similar state laws in Mississippi

and Missouri last year cost AbbVie around $33.1 million and $35 million, respectively. As the number of states adopting these kinds of laws increases, so does the irreparable harm imposed.

130. As of filing, 13 states have enacted contract pharmacy laws akin to S.B. 1414, in addition to Tennessee with material differences among and between them those state laws, complicating compliance and subjecting manufacturers to different and varying enforcement:

	AR	LA	MD	MN	MS	MO	NE	NM	ND	SD	TN	UT	WV
Restricts collection of claims data	–	✓	–	–	–	–	✓	✓	✓	✓	✓	✓	✓
Defines "340B entity" to include pharmacies	–	✓	–	–	✓	–	–	–	✓	–	✓	✓	–
Applies only to certain 340B covered entities	–	–	–	–	–	–	–	✓	–	–	–	–	–
Prohibits conditioning 340B-offers on receipt of contracts	–	–	–	–	–	–	–	–	–	–	–	✓	–
Requires "acquisition" by a pharmacy or entity	–	✓	✓	–	✓	✓	✓	✓	✓	✓	✓	✓	✓
Requires "delivery" to "any location"	–	–	–	–	–	–	✓	–	–	✓	✓	✓	✓
Prohibits "interfering" with dispensing to "eligible patients"	–	–	–	–	–	–	–	✓	✓	–	–	–	–
Prohibits use of "rebates"	–	–	–	–	–	–	–	–	✓	–	–	–	–
Restricts right to impose time limits on "replenish[ment]" orders"	–	–	–	–	–	–	–	–	–	–	–	✓	–
Applies to "an agent or affiliate"	–	–	–	–	–	✓	✓	✓		–	✓	✓	✓
Imposes criminal sanctions	–	–	✓	–	✓	–	–	✓	✓	–	✓	✓	–
Creates a private right of action	–	–	–	–	–	–	–	–	–	✓	✓	–	–

131. Even considering Tennessee's total budget for FY 2025 of $60.5 billion, the state would be hard pressed to cover AbbVie's full losses. *See* Tenn. Dep't of Fin. & Admin., Budget FY 2025–2026, https://tinyurl.com/h8ntz9z5. Therefore, the ordinary legal remedy of damages would be insufficient to make AbbVie whole. *See Eastern Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality op.) (noting that the Supreme Court has considered injunctive relief where there is a "lack of a compensatory remedy"). Regardless, any attempt to subsequently recover losses from Tennessee would likely be barred by the doctrine of sovereign immunity under the Eleventh Amendment. *See Kerchen v. Univ. of Mich.*, 100 F.4th 751, 761 (6th Cir. 2024). That alone renders AbbVie's financial losses "irreparable" harm for purposes of seeking an injunction. *Tennessee*, 104 F.4th at 613.

132. Prospective injunctive relief is appropriate because of the ongoing nature of the infringement of constitutional rights resulting from S.B. 1414. That is, the law effects a repeated and ongoing mandatory private wealth transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies for the private benefit of that pharmacy and for no recognized public use, in violation of the United States' Constitution. The law deprives AbbVie and other manufacturers of their federal rights under the actual terms of the 340B program. And, S.B. 1414 threatens to impose significant penalties upon manufacturers if they do not capitulate to Tennessee's attempt to modify the terms of that federal program. The deprivation of constitutional rights constitutes irreparable injury for purposes of a preliminary injunction. *See, e.g.*, *Bongo*, 548 F. Supp. 3d at 685; *Obama for Am.*, 697 F.3d at 436.

133. S.B. 1414's grandfather clause, stating that subsection (c) "does not apply to any requirements, prohibitions, limitations, or restrictions in place on or before June 1, 2025" does not lessen the infringement of constitutional rights. S.B. 1414, § 1(c). First, as explained *supra* ¶ _,

upon information and belief AbbVie intends to revise its policy with respect to South Dakota and North Dakota on July 1, 2025, and August 1, 2025 respectively. in order to comply with the statutes implemented in other states. And because Tennessee has no presumption against extraterritoriality, *see Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 522 (Tenn. 2005) (declining to apply presumption against extraterritoriality), there is no reason why AbbVie's policy changes in other states would be exempt from S.B. 1414's reach. Thus, any change to contract-pharmacy policies in other states will place AbbVie outside the scope of this grandfather clause. Second, there is no analogous grandfather clause provision in subsection (a), meaning AbbVie will immediately be penalized for its prior claims data related policies.

134. Granting injunctive relief here would not harm the State. It is well settled that the State has no interest in enforcing a regulation that violates federal law. *E.g.*, *Brown v. Yost*, 133 F.4th 725, 738 (6th Cir. 2025) ("[T]here is no valid state interest in enforcing unconstitutional laws."). And "it is always in the public interest to prevent violation of a party's constitutional rights." *Deja Vu of Nashville, Inc. v. Metro. Gov't of Nashville*, 274 F.3d 377, 400 (6th Cir. 2001). Moreover, there is no evidence that uninsured and needy patients—in Tennessee or anywhere else—benefit from the use of contract pharmacies, and Tennessee has no legitimate interest in enriching commercial pharmacies at the expense of manufacturers and patients.

135. Granting injunctive relief would be in the public interest. The public has no legitimate interest in enforcing unconstitutional laws, particularly those that force a transfer of private property for no public use or purpose. By contrast, the public has a strong interest in preventing states from imposing unconstitutional requirements that force the transfer of private property for the private benefit of private commercial parties. Further, the public has a strong

interest in enforcing federal law and not permitting states to change the requirements for participation in federal healthcare programs.

FIRST CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2

136. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

137. Under the Supremacy Clause of the Constitution, federal law is "supreme . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As a result, federal statutes enacted by Congress can preempt state law. *See, e.g., Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000); *Singleton v. Commonwealth of Ky.*, 843 F.3d 238, 242 (6th Cir. 2016).

138. Preemption can take multiple forms: "Federal law may preempt state law either expressly or impliedly." *State Farm Bank v. Reardon*, 539 F.3d 336, 341 (6th Cir. 2008).

139. One type of implied preemption is field preemption, which occurs where "Congress has legislated comprehensively to occupy an entire field of regulation, leaving no room for the States to supplement federal law." *Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150, 163 (2016). Field preemption occurs where Congress intends "to foreclose any state regulation in the area, even if it is parallel to federal standards." *Arizona v. United States*, 567 U.S. 387, 401 (2012).

140. Every element of the federal 340B program—from eligibility and pricing to compliance and enforcement—is governed by federal law. "Price regulation is exclusively controlled by the federal statute, and state enforcement of it would necessarily intrude on the federal scheme." *Morrissey*, 2024 WL 5147643, at *10 (internal citation omitted).

141. S.B. 1414 directly intrudes on the federal 340B scheme. Tennessee's law bars manufacturers from "limit[ing] the acquisition of a 340B drug by, or delivery of a 340B drug to" contract pharmacies, where the term "340B drug" is defined by reference to the 340B ceiling price established by federal law. § 1(c), (g)(1) (citing 42 U.S.C. § 256b(a)(1)). Thus, the Tennessee law prohibits manufacturers from conditioning their 340B offers by declining to deliver their drugs to contract pharmacies ***at a particular price***. *See Morrissey*, 2024 WL 5147643, at *9. Manufacturers violate laws like S.B. 1414 "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies." *Id.* That the state law defines the drugs in issue as "340B drug[s]" confirms that S.B. 1414 is a price regulation: "***Price*** is what distinguishes between an 'ordinary drug' and a 340B Program drug—a fact that seems to be reflected in the [Tennessee] statute itself." *Id.* (emphasis added). And, if that were not enough, S.B. 1414's catch-all provision makes abundantly clear that Tennessee's law governs price where it proscribes "any conduct" the Attorney General in his discretion believes "interfere[s] with the ability of a 340B entity ***to access discounts*** provided under the 340B program." § 1(d)(2)(7).

142. S.B. 1414 was enacted in response to manufacturers' policies, which according to HRSA and HHS result in overcharges. But the federal statute does not authorize state regulation concerning 340B pricing and who is entitled to access manufacturers' drugs at discounted 340B prices. It leaves no room for states to interfere with the carefully designed 340B program. *See Arizona*, 567 U.S. at 401 (holding that where Congress has occupied the field, state laws that impose additional obligations are preempted).

143. And to be sure, S.B. 1414 expressly regulates 340B drug pricing. The law defines "340B drug" to mean a drug that is "eligible for any ***offer for reduced prices*** by a manufacturer

under [the 340B program]." § 1(g)(1) (citing 42 U.S.C. § 256b(a)(1)). Moreover, Tennessee defines "340B entity" as "a covered entity participating in the federal 340B drug discount program," with express reference to the federal law governing 340B. *See id.* § 1(g)(2) (citing 42 U.S.C. § 256b).

144. The federal 340B statute carefully prescribes who may access 340B discounts, when, and under what conditions—including compliance with federal anti-diversion and duplicate discount requirements. The federal statute governs how prices and discounts are calculated and what obligations manufacturers must follow, requiring them to offer 340B pricing ***only*** to covered entities—not third parties. *See* 42 U.S.C. § 256b(a)(1) (stating that a manufacturer that participates in Medicaid shall agree that the price charged for covered outpatient drugs to covered entities will "not exceed an amount equal to the average manufacturer price . . . reduced by the rebate percentage described in" title XIX of the Social Security Act). *See also Arizona*, 567 U.S. at 401 (holding that where Congress has occupied the field, state laws that impose additional obligations are preempted).

145. It is foundational constitutional law that States may not regulate Congress's creations. *See McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 159 (1819) (Marshall, C.J.). A state law may not change the conditions for participation in the federal Medicare and Medicaid programs, even if it seeks to do so for laudable reasons. *See Ass'n of Banks in Ins., Inc. v. Duryee*, 270 F.3d 397, 404 (6th Cir. 2001) ("Where state and federal laws are inconsistent, the state law is pre-empted even if it was enacted by the state to protect its citizens or consumers."). Any attempt by Tennessee to regulate in this area impermissibly changes the requirements for participating in the federal 340B program and nullifies the "natural effect" of federal law. *Crosby*, 530 U.S. at 372–73.

146. Another type of implied preemption is conflict preemption. Conflict preemption occurs where it is impossible for a private party to comply with both state and federal law and also where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372–73 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (alterations omitted).

147. Tennessee's S.B. 1414 directly conflicts with federal law in multiple ways.

148. ***First,*** S.B. 1414 expands the number of entities entitled to receive 340B-discounted prices and attempts to force manufacturers to transfer their drugs to third parties—specifically, commercial pharmacies—who are not covered entities. This regulation directly conflicts with the federal 340B statute, which authorizes discounts only to covered entities and leaves manufacturers free to impose reasonable conditions on those offers. Tennessee's law expressly defines "340B entity" to "includ[e] the entity's pharmacy or pharmacies." S.B. 1414 § (h)(2). Congress specifically defined which entities qualify for 340B discounts and intentionally chose not to include pharmacies within that list, or mandate manufacturer participation in contract pharmacy arrangements. *See AstraZeneca*, 543 F. Supp. 3d at 60.

149. Tennessee's law requires manufacturers to permit any "340B entity" to receive and dispense 340B-priced drugs, thereby revoking manufacturers' freedom to include reasonable conditions on the 340B "offer" required under federal law. And it prohibits manufacturers from "impos[ing] *any* restrictions or prohibitions" on the acquisition of 340B-priced drugs to "340B entities" or contract pharmacies, instead mandating their "acquisition" or "delivery" to whatever "other location" is under contract with a 340B entity. S.B. 1414, § 1(c). This effectively forces manufacturers to transfer their discounted drugs on demand—under terms the federal statute never required and which the manufacturer would otherwise reject. And, critically, where "340B entity"

is *itself* defined to include pharmacies, that means under S.B. 1414 AbbVie could not refuse even a third party's "acquisition" of 340B-discounted drugs if a pharmacy (*not* a federally-enumerated covered entity) has a contract with a third party to "receive" such drugs. That is a gross distortion of the federal 340B program.

150. Tennessee has no lawful authority to force manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity, let alone commercial pharmacies and third parties that do not qualify as covered entities under the federal program.

151. The carefully delineated obligation for manufacturers to "offer" 340B priced drugs to covered entities is lawfully imposed by federal law solely as a condition of a manufacturer's participation in federal healthcare programs. *See* 42 U.S.C. § 256b(a)(1). To the extent that Tennessee seeks to impose, through S.B. 1414, any substantive obligation on manufacturers beyond what federal law requires, that state law obligation is preempted by federal law.

152. ***Second,*** S.B. 1414 conflicts with 340B's exclusive federal enforcement scheme by prohibiting manufacturers from demanding claims data from or initiating audits of covered entities or contract pharmacies.

153. The federal 340B statute forbids the "transfer" of 340B-discounted drugs to anyone but a covered entity's patients. 42 U.S.C. § 256b(a)(5)(ii). If a manufacturer suspects that such diversion is occurring between a covered entity and its contract pharmacy, the only way to enforce that violation is through the federal ADR process (not state or other federal law, or even through private suit). *See* 42 U.S.C. § 256b(a)(5)(B); *accord Astra*, 563 U.S. at 121-22. However, to access the federal ADR process, the 340B statute requires that a manufacturer first "conduct an audit of a covered entity … as a prerequisite to initiating [ADR] proceedings against a covered entity." 42 U.S.C. § 256b(d)(3)(B)(iv). And before a manufacturer can conduct an audit, it must

have "reasonable cause" to suspect a violation of the 340B statute—which requires access to claims data. *See* 61 Fed. Reg. 65,406, 65,407 (Dec. 12, 1996) (providing that "audits are to be performed only when there is a reasonable cause to believe that there has been a violation" of the 340B statute).

154. S.B. 1414 erects three barriers to manufacturers accessing the federal ADR process. S.B. 1414 first imposes an absolute ban on manufacturers requiring any "health information, claims or utilization data, purchasing data, payment data, or other data" as a condition of a sale of 340B-priced drugs. S.B. 1414, § 1(a)(1).

155. Next, S.B. 1414 bars manufacturers from imposing "any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities." *Id.* § 1(d)(2)(5). Where "audit" is not separately defined in S.B. 1414, this provision ostensibly prohibits manufacturers from pursuing the very federally-authorized audits they must undertake as a prerequisite to accessing the federal ADR system.[3] The regulation of the "frequency, duration, or scope of audits" is squarely within the exclusive control of the Secretary of HHS. *See* 42 U.S.C. § 256(a)(5)(C) ("A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug . . . (acting in accordance with ***procedures established by the Secretary relating to the number, duration, and scope of audits) to audit*** . . . the records of the entity." (emphasis added)). And, for example, the Secretary's guidelines governing the audit process include that the "scope" of an audit is subject to a manufacturer's submission of "a work plan" to HRSA. *See* 61 Fed. Reg. 65409 (1996). S.B. 1414 directly seeks to interfere with the contents of an audit "work plan" in direct contravention of federal regulation.

[3] To the extent that is not what S.B. 1414 § 1(d)(2)(5) means, then in the alternative it is unconstitutionally vague. *See infra* Count III.

156. Finally, S.B. 1414 prohibits manufactures from requiring "340B entit[ies]" (which, note, includes pharmacies under S.B. 1414), from "resubmit[ting or clarify[ing]" a claim after "initial adjudication,' unless that claim is "not related to the 340B program." That provision stands in direct contravention of the "good faith" dispute process required under the Secretary's audit guidelines. *See* 61 Fed. Reg. 65412 (1996) ("Prior to filing of a request for dispute with review with the Department, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of the good faith attempt to resolve the dispute."). Yet, under S.B. 1414, AbbVie will be prohibited from seeking even to "clarify" a previously submitted claim—even one in which AbbVie reasonably suspects diversion. Accordingly, it is unclear how AbbVie could ***ever*** satisfy the "good faith" inquiry process required by federal law, because doing so necessarily requires seeking "clar[ity]" into previously submitted claims.[4]

157. Together, these provisions effectively foreclose manufacturers' only avenues to pursue claims against covered entities for violations of the 340B program's requirements. The district court in *Morrisey* found that a similar claims data provision in a West Virginia law directly conflicted with federal law and was thus preempted. *See Morrisey*, 2024 WL 5147643, at *7-12. But Tennessee's law is a step even beyond the similar state law enjoined in West Virginia where it explicitly and effectively bars manufacturers from seeking audits, purports to otherwise limit manufacturers' audit rights with respect to "frequency, duration, and scope of audits" related to pharmacies, and cuts off access to the very information required to comply with the federal audit

[4] And to the extent that provision is not preempted as directly conflicting with the federal enforcement scheme, it chills AbbVie's rights to petition the government for redress as expressly contemplated by the federal statute and regulations and in violation of the First Amendment. *See infra*, Count V.

requirements. Tennessee seeks to bar manufacturers from pursuing claims against covered entities via a dispute resolution process enshrined by federal law for that very purpose and thereby seeks to directly undermine the purposes of Congress.

158. ***Third,*** S.B. 1414 installs a parallel enforcement regime, granting enforcement authority to state officials and private citizens. S.B. 1414 amends Tennessee law to make any violation of S.B. 1414's provisions a violation of the Tennessee Consumer Protection Act, which in turn grants the Tennessee Attorney General investigatory and enforcement authority over alleged violations, including criminal enforcement. S.B. 1414, § 2 (citing Tenn. Code. Ann. § 47-18-104(b)). Thus, S.B. 1414 purports to grant substantive authority to the Tennessee Attorney General over the 340B program's administration and enforcement, despite and in conflict with the comprehensive compliance and enforcement regime Congress provided and made exclusive. But Congress did not task the Tennessee Attorney General with enforcement of the 340B statute. "Congress . . . made HHS administrator of both the Medicaid Rebate Program and 340B Program." *Astra*, 563 U.S. at 120. State enforcement "would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.*

159. Tennessee law also grants ***private citizens*** a right of action to recover damages for violations of the Tennessee Consumer Protection Act and permits recovery (among other things) of treble damages. *See* Tenn. Code Ann. § 47-18-109(a). Thus, S.B. 1414 purports to grant Tennessee citizens means to enforce its provisions, which are inextricably intertwined with the federal 340B program, through private lawsuits. This state-law deputization of private citizens directly conflicts with 340B's enforcement regime consolidated in HHS. And it is an affront to Supreme Court's decision in *Astra*, which expressly held that allowing enforcement of 340B's

requirements through private litigation would undermine [HHS]'s efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 120.

160. Congress not only defined who was entitled to administer the 340B program (the Secretary of HHS, who has lawfully delegated the authority to HRSA), it also delineated which tools were available to the Secretary to ensure compliance. The 340B statute defines which audit procedures and ADR mechanisms are available under the 340B program for handling disputes among manufacturers and covered entities concerning program compliance. *See* 42 U.S.C. §§ 256b(d)(1)(B)(v), (3). Likewise, Congress outlined the penalties that apply to manufacturers who violate the statutory requirements under the 340B program and engage in "overcharging." *See id.* §§ 256b(d)(l)(B)(vi), (2)(B)(v). Tennessee's attempt to install an alternative compliance and enforcement regime, with different regulators and distinct penalties is preempted as it conflicts with the procedures detailed in the 340B statute and any lawfully promulgated federal rules implementing the statute.

161. Finally, the growing patchwork of divergent state laws exacerbates the constitutional and compliance problems. The difficulty of complying with varying state regulatory frameworks only increases as more states pass new and different laws relating to the 340B program. As of filing, 13 states have enacted contract pharmacy laws akin to S.B. 1414. State laws such as those passed by Utah, Maryland, West Virginia, Mississippi, Minnesota, Missouri, Arkansas, Kansas, Louisiana, New Mexico, Nebraska, South Dakota, and North Dakota, have material differences among and between themselves, complicating compliance by manufacturers and subjecting manufacturers to different and varying enforcement. *Compare* W. Va. Code § 60A-8-6a (extending similar prohibitions to an "agent, or affiliate" of a manufacturer), La. Rev. Stat. § 40:2883 (prohibiting a manufacturer from "prevent[ing] or interfer[ing] with ***any patient's***

choice to receive such drugs from the 340B entity" (emphasis added)), N.M. H.B. 78, § 1(A)(4), 57th Leg., 1st Sess. (2025) (covering only entities "receiv[ing] federal grant funding"), *and* Neb. L.B. 168, § 3(1), 109th Leg., 1st Sess. (2025) (compelling delivery to "***any location***" authorized by a covered entity (emphasis added)). Some states, like Tennessee, prohibit requiring the submission of claims data while others do not. *Compare* Md. Health Occupations Code § 12-6C-09.1 (prohibiting restrictions on "delivery" or "acquisition" of "340B drugs"), *with* S.B. 1414, § 1(B)(3) (restricting the collection of "any claims, utilization, purchasing or other data as a condition for allowing the acquisition of a 340B drug"). Some states, like Utah, impose criminal penalties for failure to comply while others do not. *Compare* Mo. Rev. Stat. §§ 407.095, 407.100, 407.110 (allowing for civil penalties), *with* Utah Code Ann. § 31A-2-308(9) (making violations of the statute a Class B misdemeanor). As these laws continue to accrete, administration of the 340B program and compliance with a patchwork of state laws, may become untenable, with potential catastrophic effects for the nationwide prescription drug industry. *See* Adam J. Fein, *EXCLUSIVE: The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019*, Drug Channels (June 16, 2021), https://tinyurl.com/4jdjhh7u (analyzing HRSA data to find the 340B program accounted for "16% of . . . total U.S. gross sales of brand-name drugs at list prices" in 2020).

162. Importantly, the injury here flows ***not*** from the federal program itself, but from the state's attempt to override and distort it. S.B. 1414 does not merely interact with the 340B statute—it imposes new obligations that conflict with the structure Congress created. Here, AbbVie does not challenge Congress's design or dispute the requirements imposed under federal law. Rather, it challenges Tennessee's effort to rewrite those requirements by transforming a conditional federal offer into a mandatory, state-enforced sale on terms the federal statute does not require (and which may in fact even *violate* the federal statute), and by expressly and effectively

foreclosing AbbVie's ability to access its only enforcement mechanism: federal ADR. Tennessee's law does not fill a gap—it tears through the fabric of the federal scheme Congress designed to be uniform, voluntary, and within the exclusive federal enforcement authority of HHS.

SECOND CLAIM FOR RELIEF

Prospective Injunctive Relief and Declaratory Relief – Violation of Takings Clause, U.S. Const. amend. V, cl. 4

163. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

164. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend. V; *see also Chicago, Burlington & Quincy Ry. v. Chicago*, 166 U.S. 226, 234–35 (1897) (incorporating and making applicable to states the Takings Clause of the Fifth Amendment through the Due Process Clause of the Fourteenth Amendment).

165. The Takings Clause extends to both real and personal property. *Horne*, 576 U.S. at 358. It is not limited to instances when the government physically appropriates property for its own use through eminent domain. A taking can also occur through legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

166. Under the Constitution, the government has no authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo*, 545 U.S. at 477 (explaining that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation"). Such private takings are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798)

("[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B").

167. "Whenever a regulation results in a physical appropriation of property, a *per se* taking has occurred." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021). Statutes or regulations that mandate the physical transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation.

168. Tennessee's S.B. 1414 appropriates AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies. On its face, S.B. 1414 prohibits manufacturers from "deny[ing]," "restrict[ing]," "prohibit[ing]," or "otherwise limit[ing]" the "acquisition . . . of a 340B drug" by a "340B entity," including contract pharmacies and any "other location that is under contract with" a 340B entity. S.B. 1414 § 1(c). Moreover, a close reading of the statutory text reveals that AbbVie could even be held liable—and face misdemeanor penalties—for refusing to transfer drugs ordered by a private pharmacy to a private ***third*** party. As explained above, where Tennessee's law defines "340B entity" to include "pharmacies" of covered entities, *id.* § 1(g)(2), under section 1(c), a manufacturer could be liable and compelled to sell their drugs at steeply discounted prices where the "340B entity" pharmacy directs the transfer of the drugs to a private third party "under contract with" that pharmacy. If Tennessee requires manufacturers to provide their drugs to commercial pharmacies or other private entities at below-market prices—by purporting to add that as a state-law obligation attached to the federal 340B scheme—then Tennessee is engaged in an impermissible per se violation of the Constitution's Takings and Due Process Clauses.

169. S.B. 1414 mandates that pharmaceutical manufacturers provide 340B-priced drugs at below-market prices, depriving them of control over their own pricing structures and revenue.

The PhRMA Impact Statement confirms that manufacturers' prices for drugs sold through the 340B program are significantly below the market price and that state already forgoes rebate savings of approximately $54 million as a result of the 340B program. *See* PhRMA Impact Statement, *supra*, at 1.

170. S.B. 1414 compels sales or transfer of AbbVie's drugs at the 340B-discounted that, in the absence of S.B. 1414, would not occur. AbbVie's offer is made conditional upon covered entity's acceptance of AbbVie's contract pharmacy policy. In the absence of S.B. 1414, if a covered entity counteroffered with a term requiring unlimited contract pharmacy access, AbbVie would simply refuse that covered entity's counteroffer and no sale at the 340B-discounted price would take place. However, when S.B. 1414 is in force, it would operate to compel AbbVie to accept the counteroffer and complete the sale at the discounted price on terms AbbVie would not otherwise have agreed to.

171. S.B. 1414 expands the federal 340B program requirements in a way that shifts financial burdens onto manufacturers, reducing revenue and eliminating rebate offsets, without just compensation and with no justified public use.

172. In the alternative, S.B. 1414 effectuates a partial regulatory taking.

173. In *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124 (1978), the Supreme Court recognized that a regulatory taking requires consideration of a flexible three-factor test: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment backed expectations, and (3) the "character of the governmental action."

174. S.B. 1414's purported requirement that manufacturers transfer their drugs to commercial pharmacies is constitutionally impermissible because it requires the physical

acquisition of AbbVie's drugs by another private party for no public purpose or use; imposes significant financial losses on AbbVie and other manufacturers; interferes with drug manufacturers' reasonable investment backed expectations; and serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.

THIRD CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Due Process Clause, U.S. Const. art. XIV

175. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

176. The Due Process Clause of the Fourteenth Amendment provides that no State may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1.

177. A statute is unconstitutionally vague if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or "if it authorizes or even encourages arbitrary and discriminatory enforcement." *Tennessee Educ. Ass'n v. Reynolds*, 732 F. Supp. 3d 783, 806 (M.D. Tenn. 2024) (citing *Platt v. Bd. of Commr's on Grievances and Discipline*, 894 F.3d 235, 246 (6th Cir. 2018)). "[L]aws that include criminal prohibitions typically require a higher level of specificity than purely civil laws." *Id.*

178. S.B. 1414's prohibitions are unconstitutionally vague because they fail to provide manufacturers with fair notice of what conduct is prohibited and invite arbitrary and discriminatory enforcement.

179. ***First,*** S.B. 1414 prohibits "***any***" conduct that the "attorney general and reporter" determines "interfere[s] with the ability of a "340B entity to access discounts provided under the 340B program." S.B. 1414 § 1(a)(6). This provision impermissibly delegates open-ended

enforcement discretion to a state official without clear standards, leaving manufacturers to guess what conduct the Attorney General might consider "interference." The prohibition is particularly problematic because manufacturers have no ability to verify or confirm which pharmacies have valid 340B claims at the time of dispensing, and because pharmacies often commingle inventory and determine patient eligibility only after-the-fact.

180. ***Second,*** S.B. 1414 prohibits manufacturers from "impos[ing] any requirements relating to inventory management systems of 340B drugs, unless such requirement is required by [HHS] or applicable state law." S.B. 1414 § 1(a)(3). But the statute does not define what constitutes a "requirement," how it must "relate" to an inventory management system, or even what an "inventory management system" is. Manufacturers could be exposed to liability for routine supply-chain practices, operational policies, or even basic compliance steps—without any clear way to know whether those practices "relate" to inventory systems under the statute's nebulous terminology. This kind of provision would also foreclose AbbVie's ability to require, for example, even that covered entities maintain title to drugs held by contract pharmacies in compliance with federal regulations—presuming that such a requirement could be interpreted as "relating to inventory management systems." *See* 61 Fed. Reg. 43,549, 43,553 (Aug. 23, 1996) (explaining that the covered entity purchases the drugs, and must retain title and responsibility for them even after directing shipment to the contract pharmacy).

181. ***Third,*** S.B. 1414's prohibition on "limit[ing] the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity ***or other location*** that is under contract with, ***or otherwise authorized by***, a 340B entity" is likewise unconstitutionally vague. S.B. 1414, § 1(c) (emphasis added). The law defines "340B entity" to include a covered entity and its pharmacies but imposes no geographic limitation. Because S.B. 1414 could be read to reach any third party contracting

with a covered entity or pharmacy anywhere in the country, the scope of prohibited "limit[ation]" is unbounded. AbbVie would have no way of predicting or understanding the reach or application of S.B. 1414. Worse still, S.B. 1414 distinguishes between contractual and some undefined form of authorization—without defining what qualifies as "authorization." *See id.* (restricting limits to locations "***otherwise authorized***" by the covered entity). There is no mechanism for manufacturers to monitor, verify, or even be informed of informal, verbal, or private authorizations. AbbVie could unknowingly violate the statute simply because a covered entity verbally authorized a pharmacy (or "other location")—or later withdrew that authorization without notice. AbbVie neither has access to these contracts nor the ability to verify ad hoc authorizations, yet it is expected to conform its conduct accordingly under the threat of liability. Such shifting, undocumented authorizations create an unacceptable risk of arbitrary enforcement and deprive AbbVie of fair notice regarding its obligations.

182. ***Fourth,*** in the alternative and to the extent the statute's prohibition related to "impos[ing] any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities" does not refer to the *federal* audit process, then it is unconstitutionally vague, and unclear in multiple respects. *See* S.B. 1414 § 1(a)(4).

183. S.B. 1414 vaguely references "providers that are not 340B entities" as the comparator group without defining what that includes. This class could include any number of entities—pharmacies unaffiliated with a covered entity, clinics and hospitals outside the 340B program entirely, or simply any healthcare provider. Without a clear comparator group, manufacturers are left in the dark as to how they must structure their compliance efforts to avoid civil and criminal penalties.

184. The statute is also unclear on whether the requirements "not imposed" on non-340B "entities" are requirements that are not imposed by ***AbbVie*** or by ***any drug manufacturer***. Thus, the text might be reasonably read to bar AbbVie from imposing on a covered entity any audit requirement that ***another drug manufacturer*** has declined to impose on another class of pharmacy or provider. But under that reading, AbbVie has no way of knowing what is and what is not prohibited at any given moment. Healthcare facilities not participating in the 340B program are not required to share any type of information with manufacturers. Unlike 340B-covered entities, other providers are not subject to HRSA oversight or 340B-specific data requirements. As a result, AbbVie cannot reasonably know whether an audit practice directed at a covered entity is different from what would be imposed on a non-340B provider—and therefore whether they are violating Tennessee's law. The statute's silence on this point effectively sets a trap: manufacturers could be penalized for imposing an audit standard without any practical ability to discern whether they have crossed an invisible line.

185. To make matters worse, the statute does not define what specific actions, conditions, or expectations would qualify as "requirements relating to" audits. Auditing in the 340B context is a specialized practice tied to program-specific compliance obligations, not a routine industrywide activity. But by using capacious language like "relating to," Tennessee is painting with an incredibly broad brush that leaves AbbVie with little to no notice as to what conduct ***specifically*** is barred.

186. Nor does S.B. 1414 contain a scienter requirement such as "knowledge" or otherwise, as for example Tennessee's claim for tortious interference does. *See, e.g.*, *Whalen v. Bourgeois*, 2014 WL 2949500, at *10 (Tenn. Ct. App. June 27, 2014) (citations omitted). This raises the possibility of liability for accidental or unintended conduct.

187. These provisions create an unconstitutional risk of arbitrary enforcement. AbbVie is left to guess whether routine practices—like requesting inventory obligations or confirming compliance with federal regulations—constitute prohibited "requirements relat[ed] to inventory management systems" under S.B. 1414. "[I]nventory management" could plausibly encompass reporting formats, physical storage procedures, shipment logistics, audit processes, or even stock replenishment models. AbbVie has no clear guidance on where acceptable business practices end and prohibited conduct begins. Further, S.B. 1414's carveout for actions "required by [HHS] or applicable state law" offers no stable standard because it requires AbbVie to know and correctly interpret all relevant HHS policies and Tennessee state laws at the time of its conduct—an impossible burden. Without clear boundaries, AbbVie faces an ongoing risk of enforcement based on interpretations of an indeterminate standard.

188. S.B. 1414 is thus unconstitutionally vague on its face. It fails to provide sufficient notice as to what conduct is prohibited, particularly in the complex and highly regulated context of 340B transactions. Persons of common intelligence must guess at its meaning and may well offer vastly different yet reasonable interpretations of its scope. The ambiguity is especially concerning given the statute's civil penalties and the risk that protected commercial speech could be chilled by uncertainty over what constitutes prohibited conduct.

FOURTH CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Commerce Clause, U.S. Const. art. 1 § 8

189. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

190. Central to our federal constitutional structure is the principle that "all States enjoy equal sovereignty." *Shelby County v. Holder*, 570 U.S. 529, 535 (2013). "A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted

or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (citation omitted). This basic principle manifests in the several constitutional provisions that limit the power and authority of the states in relation to each other. *See, e.g.*, U.S. Const. art. I, § 10 (denying certain powers states otherwise might enjoy as sovereign nations); art. IV, § 1 (Full Faith and Credit Clause); art. IV, § 2, cl. 1 (Privileges and Immunities Clause); art. IV, § 2, cl. 2 (interstate extradition).

191. The Commerce Clause—which grants Congress alone the "Power . . . To regulate Commerce . . . among the several States," U.S. Const. art. I, § 8, cl. 3—also implicitly limits the extraterritorial authority of the States. The Supreme Court has held that the Commerce Clause prohibits states from directly "control[ling] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst.*, 491 U.S. 324, 335–36 (1989); *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986).

192. The Court recently clarified the reach of its "dormant" Commerce Clause jurisprudence, holding that state regulation of conduct within its borders that may also have an "extraterritorial effect" in other states are not categorically barred. *Nat'l Pork*, 598 U.S. at 374. But the Court also made clear that it did not disturb its prior precedent finding state laws unconstitutional where they "directly regulated out-of-state transactions by those with no connection to the State." *Id.* at 376 n.1 (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 641–43 (1982)).

193. The Sixth Circuit has adopted a two-step analysis to evaluate challenges under the dormant Commerce Clause. *Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 369 (6th Cir. 2013). The court first determines whether the "state statute directly regulates or discriminates against interstate commerce, or [whether] its effect is to favor in-state economic interests over out-of-state

interests." *Id.* at 369–70 (quoting *Brown-Forman*, 476 U.S. at 579). If the law is "neither discriminatory nor extraterritorial, then the court must apply the balancing test established in *Pike*," upholding the law "unless the burden it imposes upon interstate commerce is 'clearly excessive in relation to the putative local benefits.'" *Id.* at 370 (quoting *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 644 (6th Cir. 2010)). The Sixth Circuit recognizes that a state law is "virtually per se invalid under the dormant Commerce Clause" when "the law regulates extraterritorial commerce." *Id.* at 373 (quoting *Int'l Dairy*, 622 F.3d at 645).

194. Tennessee courts look to the plain text of a statute when assessing its territorial reach. Without "any language indicating that the legislature intended that the scope of the act be limited to *intra*state commerce," instead of *inter*state commerce, Tennessee courts decline to apply a presumption against extraterritoriality. *See Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 522 (Tenn. 2005) (emphasis added) ("Had the legislature intended such a [territorial] limitation, the legislature simply could have included the limitation in the act.").

195. For that reason, S.B. 1414 runs afoul of dormant Commerce Clause principles on all three fronts.

196. ***First***, S.B. 1414 discriminates against interstate commerce in favor of in-state commerce. The central aim of Tennessee's law is to privilege covered entities and pharmacies over out-of-state manufacturers by forcing the manufacturers to provide drugs at significantly reduced prices to covered entities under terms not agreeable to them, resulting in the compelled transfer of those drugs to any pharmacy or "other location"—regardless of connection to Tennessee. That significantly burdens out-of-state manufacturers like AbbVie for the direct benefit of in-state entities by compelling AbbVie to extend them bargain basement pricing.

197. Tennessee cannot articulate any valid justification for discriminating against out-of-state manufacturers. As detailed above, compelling AbbVie to transfer more drugs at reduced costs to contract pharmacies does not benefit 340B patients—it serves only to create arbitrage profits for commercial pharmacy chains.

198. Tennessee's use of a federal program to benefit some in-state covered entities and contract pharmacies themselves at the expense of out-of-state manufacturers like AbbVie, "amounts to 'simple economic protectionism'" that the Supreme Court recently affirmed to be an illegitimate legislative interest. *Nat'l Pork*, 598 U.S. at 372 (quoting *Brown-Forman*, 476 U.S. at 580). By protecting local economic interests at the expense of interstate commerce, Tennessee engages in economic protectionism, precisely what the dormant Commerce Clause doctrine aims to prevent.

199. ***Second***, S.B. 1414 imposes a burden on interstate commerce that outweighs any conceivable benefit to in-state commerce. *Davis*, 553 U.S. at 353 (2008). S.B. 1414 places an improper thumb on the scale and tilts the bargaining power in favor of some in-state pharmacies and covered entities at the expense of out-of-state manufacturers.

200. In addition to directly regulating out-of-state transactions, S.B. 1414 violates dormant Commerce Clause principles because courts will strike down statutes that "regulate[] even-handedly to effectuate a legitimate local public interest," when "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits." *Jelovsek v. Bredesen*, 545 F.3d 431, 437 (6th Cir. 2008) (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)); *see also Davis*, 553 U.S. at 353 (finding that dormant Commerce Clause jurisprudence prohibits "nondiscriminatory burdens on commerce . . . that . . . clearly outweigh the benefits of a state or local practice").

201. S.B. 1414 poses a very high burden on the 340B program and the national prescription drug industry as a whole. Forcing manufacturers across the country to sell to any covered entity or contract pharmacy will result in transactions that may be fully permissible in the state where they occur but that become subject to enforcement actions in Tennessee. Therefore, S.B. 1414 effectively compels manufacturers to sell discounted drugs nationwide based on Tennessee's mandates, imposing an extraterritorial economic burden.

202. But even if passed to help ensure 340B-eligible patients receive discounts on their prescription medications, S.B. 1414 will actually have the opposite effect. Manufacturers, no longer able to impose conditions on who actually receives their drugs, will be unable to stop abuses that result in covered entities requiring "insured patients to pay *more* for their prescriptions at contract pharmacies so the covered entity can generate 340B funds." Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, Food & Drug L. Inst. Update Mag. (Fall 2022) (emphasis added), https://tinyurl.com/yc6fnc5c. S.B. 1414 provides no legitimate benefit to the State of Tennessee and thus cannot outweigh the high burden it places on the national drug industry and the 340B program itself.

203. ***Third***, S.B. 1414 has the practical effect of extraterritorial control on interstate commerce. *See Healy*, 491 U.S. at 336 (concluding that "a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature"). Covered entities often enter contract pharmacy arrangements with pharmacies located outside the state. For example, a Tennessee covered entity may have contract pharmacies in Hawaii. And a Hawaii covered entity may have contract pharmacies in Tennessee.

204. The statute's definition of "340B entity" sweeps broadly to include covered entities' pharmacies without any geographic limitation. *See* S.B. 1414 § 1(g)(2). Likewise, manufacturers are forbidden from restricting "acquisition . . . or delivery of a 340B drug" not only to a "340B entity," but also to vaguely defined "***other location[s]***" authorized by covered entities—again, with no state nexus requirement. *See id.* § 1(c).

205. S.B. 1414 thus prohibits ***any*** manufacturer across the country from imposing conditions to the transactions between itself and ***any*** covered entity, pharmacy, or "other location" authorized by a covered entity across the country, regardless of whether such manufacturer or entity has any nexus to Tennessee. S.B. 1414 does not establish a sufficient nexus for the state to regulate manufacturers' nationwide practices and impose restrictions on their national supply chains. *S. Dakota v. Wayfair, Inc.*, 585 U.S. 162, 188 (2018) (finding that substantial nexus requires more than just sales to in-state residents; it requires an actual connection to the state).

206. S.B. 1414's text includes no express limitation on its territorial reach. Instead, its defined terms sweep broadly and appear to cover participation in the federal 340B program nationwide. *See Freeman Indus.*, 172 S.W.3d at 522.

207. Indeed, on its face, the Tennessee law could govern a transaction between a drug manufacturer located in Illinois, its wholesaler in Kentucky, and a California pharmacy that contracts with a covered entity in Florida and that dispenses the drug to a Texas resident. Such broad reach results in Tennessee's improper interference with interstate commerce in violation of dormant Commerce Clause doctrine.

FIFTH CLAIM FOR RELIEF

Declaratory/Injunctive Relief –
Violation of Free Speech and Petition Clauses, U.S. Const. amend. I.

208. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

209. The U.S. Constitution's First Amendment prohibits the government from "abridging the freedom of speech," and expressly protects the right to "petition the government for a redress of grievances." U.S. Const. amend. I; *see Gitlow v. New York*, 268 U.S. 652, 666 (1925) (applying First Amendment's protections against the States via the Fourteenth Amendment).

210. The free-speech protection is particularly powerful for regulations that "target speech based on its communicative content." *Nat'l Inst. of Fam. & Life Advocates v. Becerra*, 585 U.S. 755, 766 (2018) (quoting *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015)). It is axiomatic that "governments have 'no power to restrict expression because of its message, its ideas, its subject matter, or its content.'" *Id.* Likewise, the "right to petition"—including the right to reasonably access courts and other government adjudicators—is fundamental to the "very idea of a government, republican in form." *See BE&K Constr. Co. v. NLRB*, 536 U.S. 516, 524-25 (2002); *see also Gable v. Lewis*, 201 F.3d 769, 771 (6th Cir. 2000) (holding that "the right to petition extends to all departments of the Government," including "administrative agencies" (quoting *Cal. Transport v. Trucking Unlimited*, 404 U.S. 508, 510 (1972))); *Holzemer v. City of Memphis*, 621 F.3d 512, 521 (6th Cir. 2010) (holding that right to petition protected private citizen's attempt to "operate his business" and navigate government regulatory process).

211. The First Amendment's protections extend to commercial speech. *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). Even "speech which does

no more than propose a commercial transaction" is entitled to First Amendment protection. *Id.* (quoting *Pittsburgh Press Co. v. Human Rels. Comm'n*, 413 U.S. 376, 385 (1973)).

212. AbbVie engages in First-Amendment protected speech when it expresses its views about the 340B program and seeks to exercise its rights ***under*** that program. The First Amendment protects AbbVie's right to speak about abuses of the 340B program by commercial contract pharmacies, covered entities, and others. It protects AbbVie's right to express its views on necessary terms of 340B offers and the duties of 340B participants. And it protects AbbVie's right to speak to other entities—including covered entities and contract pharmacies who purchase AbbVie's drugs—about the terms of 340B offers and about disputes over sales made at the 340B price. *See, e.g.*, *Hendrickson USA, LLC v. NLRB*, 932 F.3d 465, 470 (6th Cir. 2019) (citing *NLRB v. Gissel Packing Co.*, 395 U.S. 575, 617 (1969)) (noting that First Amendment protects employers' right to communicate with employees about merits of labor dispute in order to influence its outcome).

213. Tennessee's S.B. 1414 unlawfully restricts AbbVie's constitutionally protected speech and chills AbbVie's ability to exercise its rights under the federal 340B program to access the federal audit procedure. For example, S.B. 1414 prohibits AbbVie from requesting that a 340B entity "clarify" its claim for 340B reimbursement. S.B. 1414 §§ 1(a)(2), (g)(3). By restraining AbbVie from even seeking "clari[ty]" from 340B entities (which includes pharmacies under S.B. 1414), the State robs AbbVie of its right to communicate effectively with its sales counterparts and express its dissatisfaction or confusion with, or simply to ask for more information about, a given claim. AbbVie regularly asks follow-up questions related to invoicing and replenishment, including with respect to pharmacy benefit managers, TPAs, and others, to ensure (among other

things, including contractual obligations) compliance with the federal prohibition on duplicate discounting.

214. Moreover, the federal audit regulations specifically call for "good faith" inquiry as a mandatory predicate to seeking HRSA resolution, and part of that good faith inquiry necessarily requires manufacturers like AbbVie to seek "clar[ity]" on claims from covered entities. *See* 61 Fed. Reg. 65412 (1996) (requiring parties "provide copies of any documents supporting its claim and evidence that a good faith effort was made to resolve the dispute"). So S.B. 1414 does not only chill AbbVie's speech—it prevents AbbVie from accessing the federal agency's dispute-resolution process in violation of the Petition Clause.

215. Finally, Tennessee's law broadly forbids AbbVie from "either directly or indirectly" imposing "any requirement determined by the attorney general and reporter to interfere with the ability of a 340B entity to access discounts provided under the 340B program." S.B. 1414 § 1(a)(6). In similarly sweeping terms, the law bars AbbVie from imposing other "requirements" and "limitations" on 340B entities. *See* S.B. 1414 § 1(a), (c). These vague, open-ended proscriptions reach AbbVie's protected speech and chill its constitutionally protected ability to communicate with prospective business partners, pharmacies, and the public.

216. S.B. 1414's speech restrictions are content-based. After all, the law prohibits certain speech about a particular topic—the 340B program—but does not prohibit speech that is "not related to the 340B program." S.B. 1414 § 1(a)(2); *see id.* § 1(a)(6). "[C]ontent-based restrictions on constitutionally protected speech are anathema to the First Amendment and are deemed 'presumptively invalid.'" *Bible Believers v. Wayne County*, 805 F.3d 228, 248 (6th Cir. 2015) (en banc) (citation omitted). No such law can survive "unless the restriction is narrowly tailored to be the least-restrictive means available to serve a compelling government interest." *Id.*

217. Tennessee lacks any legitimate interest—much less a compelling one—in prohibiting AbbVie from urging 340B entities against abusing the 340B system. It certainly lacks any such interest in preventing AbbVie from seeking "clar[ity]" from 340B entities who demand reimbursement. *See* S.B. 1414 §§ 1(a)(2), (g)(3); *accord Shapero v. Ky. Bar Ass'n*, 486 U.S. 466, 472 (1988) ("Commercial speech that is not false or deceptive and does not concern unlawful activities may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest." (citations and ellipsis omitted)). Accordingly, S.B. 1414 violates the First Amendment.

PRAYER FOR RELIEF

WHEREFORE, AbbVie prays for the following relief:

1. A declaration, order, and judgment holding S.B. 1414 unlawful because it is preempted by federal law and unconstitutional under the Supremacy Clause;
2. A declaration, order, and judgment declaring that S.B. 1414 effects an impermissible taking of AbbVie's property for private benefit;
3. A declaration, order, and judgment declaring that S.B. 1414 violates the Due Process Clause;
4. A declaration, order, and judgment declaring that S.B. 1414 violates the Commerce Clause;
5. A declaration, order, and judgment declaring that S.B. 1414 violates the First Amendment;
6. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to unconditionally provide 340B pricing to covered entities or contract pharmacies or transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies;

7. A preliminary and permanent injunction enjoining the Tennessee Attorney General from enforcing S.B. 1414;

8. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

9. Any other relief that this Court deems just and proper.

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Respectfully submitted,

/s/ Minton P. Mayer

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